NOTICES OF FINAL RULEMAKING

The Administrative Procedure Act requires the publication of the final rules of the state's agencies. Final rules are those which have appeared in the *Register* first as proposed rules and have been through the formal rulemaking process including approval by the Governor's Regulatory Review Council or the Attorney General. The Secretary of State shall publish the notice along with the Preamble and the full text in the next available issue of the *Register* after the final rules have been submitted for filing and publication.

NOTICE OF FINAL RULEMAKING

TITLE 4. PROFESSIONS AND OCCUPATIONS

CHAPTER 23. BOARD OF PHARMACY

Editor's Note: The following two Notices of Final Rulemaking were exempt from Executive Order 2012-03 as issued by Governor Brewer. (See the text of the executive order on page 2931.)

[R13-152]

PREAMBLE

1. Articles, Parts, or Sections Affected (as applicable) — **Rulemaking Action**

R4-23-110	Amend
R4-23-674	Amend
R4-23-701	Amend
R4-23-701.01	Amend
R4-23-701.02	Amend
R4-23-701.04	New Section
R4-23-702	New Section
R4-23-703	Amend
R4-23-704	New Section

2. Citations to the agency's statutory rulemaking authority to include the authorizing statute (general) and the implementing statute (specific):

Authorizing statute: A.R.S. §§ 32-1904(A)(1) and A.R.S. 32-1904(B)(3)

Implementing statute: A.R.S. §§ 32-1904(A)(1) and A.R.S. 32-1904(B)(3)

3. The effective date of the rule:

November 10, 2013

4. Citations to all related notices published in the *Register* as specified in R1-1-409(A) that pertain to the record of the final rulemaking packages:

Notice of Rulemaking Docket Opening: 18 A.A.R. 3263, December 14, 2012

Notice of Proposed Rulemaking: 19 A.A.R. 258, February 22, 2013

5. The agency's contact person who can answer questions about the rulemaking:

Name:	Sandra Sutcliffe, Compliance Officer
Address:	Board of Pharmacy 1616 W. Adams Phoenix, AZ 85007
Telephone:	(602) 771-2727
Fax:	(602) 771-2749
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Web site:	www.azpharmacy.gov

6. An agency's justification and reason why a rule should be made, amended, repealed or renumbered, to include an explanation about the rulemaking:

In August 2005 rules R4-23-701, R4-23-701.01, R4-23-701.02, R4-23-701.03, and R4-23-703 underwent the Five-Year Rule Review, and the Board recommended a task force be appointed. A task force was appointed by the Board in 2008 to review the rules and several meetings were held before the Governor's moratorium on rulemaking was

implemented in March 2009. The rules were again due for the Five-Year Rule Review in August 2010, however the rulemaking moratorium was still in effect through September 2011. The Board appointed another task force in 2012 to review the rules and is now ready to make changes to those rules.

The rulemaking will amend rule R4-23-110 Definitions by adding or amending definitions to support changes in Article 7 rules. These definitions include "assisted living facility", "automated dispensing system", "emergency drug supply unit", "hospice inpatient facility", "long-term care facility", and "resident".

The rulemaking will amend rule R4-23-674 Limited-service Long-term Care Pharmacy by removing the requirement that a long-term care consultant pharmacist be employed by or contracted with the provider pharmacy. The rulemaking includes changes to the policies and procedures section. Those references are in R4-23-674(B)(1)(2) and (F)(11).

The rulemaking will amend rule R4-23-701 Long-term Care Facilities Pharmacy Services: Consultant Pharmacist by including the requirement that a long-term care consultant pharmacist in an Arizona facility be licensed by the Board, and clarifying the long-term care consultant pharmacist's responsibilities to the facility. Those references are in R4-23-701(A), (B), (C), and (D).

The rulemaking will amend rule R4-23-701.01 Long-term Care Facilities Pharmacy Services: Provider Pharmacy by removing the statute citations for labeling in generic substitution and for labeling of drugs dispensed by a hospital pharmacy. Those references are in R4-23-701.01(2). The rulemaking changes the development of policies and procedures for drug recalls to the provider pharmacy, and clarifies the drug recall procedures that require the discontinuation of therapy are for those drugs being recalled at the patient level. Those references are in R4-23-701.01(4). The rulemaking adds the requirement that previously dispensed drugs are not to be repackaged, and deletes the reference to rebates. Those references are in R4-23-701.01(5).

The rulemaking will amend rule R4-23-701.02 Long-term Care Facilities Pharmacy Services: Emergency Drugs by adding the requirement that drugs contained in an emergency drug supply unit remain the property of the provider pharmacy, and any controlled substances in the emergency drug supply units are counted in all required inventories. Those references are in R4-23-701.02(A). The rulemaking adds a definition for emergency drug supply unit, and excludes the use of an emergency drug supply unit for the provision of routine drugs. The rulemaking clarifies that drugs provided in an emergency drug supply unit can be manufacturer's unit of use or prepackaged by the provider pharmacy with specific labeling. Those references are in R4-23-701.02(B). The rulemaking changes the exterior labeling of the emergency drug supply unit to requiring only the date of the earliest drug expiring, clarifies that a pharmacist is responsible for the last inspection of the emergency drug supply unit, and adds a security seal or lock requirement. Those references are in R4-23-701.02(C). The rulemaking changes the exchange or restocking requirements of an emergency drug supply unit to weekly or as necessary, and adds that restocking at the facility is done by a pharmacist or under the direct onsite supervision of a pharmacist. Those references are in R4-23-701.02(D). The rulemaking adds a new section for the use of an automated emergency drug supply unit. Those references are in R4-23-702(E).

The rulemaking will add a new rule section R4-23-701.04 Long-term Care Facilities Pharmacy Services: Automated Dispensing Systems to allow the use of an automated dispensing system within a long-term care facility. The rulemaking would allow an automated dispensing system to be placed at a long-term care facility for the storage and dispensing of solid oral dosage forms (tablets and capsules) from canisters equipped with microchip or other technologies that is coded to the specific drug within the canister. Drugs within the automated dispensing system would be available for administration to a resident of the long-term care facility only after a pharmacist received and verified a prescription. The automated dispensing system would be required to label each individual drug packet with a resident specific label, and maintain an electronic record of transactions. Access to the system would be administered and controlled by the provider pharmacy.

The rulemaking will add a new rule section R4-23-702 Hospice Inpatient Facilities to outline the criteria for the provision of contracted pharmacy services in a hospice inpatient facility.

The rulemaking will amend rule R4-23-703 Assisted Living Facilities by adding the statute citation for the labeling of controlled substances. Those references are in R4-23-703(B) and (C). The rulemaking adds the requirement that emergency drug supply units or automated dispensing systems are not to be placed in an assisted living facility, and deletes the reference to rebates. Those references are in R4-23-703(F). The rulemaking adds the requirement that previously dispensed drugs are not to be repackaged. Those references are in R4-23-703(G).

The rulemaking will add a new rule section R4-23-704 Customized Patient Medication Packages to allow the packaging of two or more prescribed drugs in a single container.

The rules will include format, style, and grammar necessary to comply with the current rules of the Secretary of State and the Governor's Regulatory Review Council.

7. A reference to any study relevant to the rule that the agency reviewed and either relied on or did not rely on in its evaluation of or justification for the rule, where the public may obtain or review each study, all data underlying each study, and any analysis of each study and other supporting material:

The agency did not review or rely on any study relevant to the rule.

8. A showing of good cause why the rulemaking is necessary to promote a statewide interest if the rulemaking will

diminish a previous grant of authority of a political subdivision of this state:

Not applicable.

9. A summary of the economic, small business, and consumer impact:

The amended rules will impact the Board, pharmacies, pharmacists, long-term care facilities, hospice inpatient facilities, and assisted living facilities. The amended rules' impact on the Board will be the usual rulemaking-related costs, which are minimal.

The Board estimates the administrative-related costs to update the policies and procedures due to the amended rules will have a minimal economic impact on pharmacies.

The amended rules allow for the restocking of an emergency drug supply unit on a weekly basis rather than every 48 hours. This will provide a moderate economic benefit to pharmacies by reducing personnel and transportation costs.

The amended rules allow for the use of automation for emergency drug supply units in long-term care facilities and hospice inpatient facilities, however the use of automation is discretionary not mandatory.

The amended rules allow for the use of automated dispensing systems in long-term care facilities, however the use of automation is discretionary not mandatory.

The Board believes that approval of the rules benefits the public, Board, pharmacies, pharmacists, long-term care facilities, hospice inpatient facilities, and assisted living facilities by establishing clear standards governing the practice of consultant pharmacists and pharmacies that provide pharmacy services to long-term care facilities, hospice inpatient facilities, and assisted living facilities.

We could not find a less intrusive or less costly alternative method to achieve the final rulemaking. The method we chose imposes minimal costs on the agency and pharmacies. The only alternative available is to not do the rulemaking, which would leave outdated sections in rule.

10. A description of any changes between the proposed rulemaking, to include supplemental notices, and the final rulemaking:

There are no substantial changes in the final rules from the proposed rules. There are minor changes to style, format, grammar, and punctuation requested by G.R.R.C. staff.

11. An agency's summary of the public or stakeholder comments made about the rulemaking and the agency response to the comments:

A public hearing was held on March 25, 2013. Matt Sneller VP of Pharmacy Affairs for Talyst Kirkland, WA and Jeff Hohl President and COO One Point Patient Care Pharmacy Tempe, AZ provided public testimony. Written comments were received from R. Blake Griese Assistant General Counsel AlixaRx Plano, TX, as well as from Matt Sneller Talyst. Comments were received on the following proposed rule sections: R4-23-701.02(D)(4), R4-23-701.04(B)(3), R4-23-701.04(B)(4), R4-23-701.04(D)(3)(a)(i), and R4-23-702.

A comment was received on section R4-23-701.02(D)(4) asking the Board to keep the old language of allowing "pharmacy personnel" to restock an emergency drug supply unit. In the alternative, the commenter asked the Board to consider amending the "employed pharmacist" language to read "employed by or contracted with". The commenter also requested the Board consider amending the "employed pharmacist" language in R4-23-701.04(D)(3)(a)(i).

For sections R4-23-701.04(B)(3) and R4-23-701.04(B)(4), all three individuals asked the Board to reconsider the proposed rules for automated dispensing systems concerning the restriction on CII medications and the use of an automated dispensing system as an emergency drug supply unit.

A comment was received on section R4-23-702 asking the Board to reconsider the proposed rule prohibiting the use of an automated dispensing system in a hospice inpatient facility.

The Board reviewed the comments to the proposed rules at the May 9, 2013 Board meeting. The Board members discussed the information reviewed by the task force members in developing the proposed rules. The Board President indicated he did not feel the task force should meet again to discuss the proposed rules because the comments do not affect patient safety and were made for financial reasons. The Board member who chaired the task force indicated the task force was a diverse group and a seasoned team of practitioners. The chairperson stated the practitioners did not have concerns with the regulations and does not see a need to change the proposed rules because of manufacturer comments. One Board member stated that the rules vary in different states, and he is comfortable with the decisions the task force made. On motion, the Board unanimously approved to continue the rulemaking process for the proposed long-term care rules with no changes. The Notice of Final Rulemaking and Economic Impact Statement were unanimously approved by the Board at the June 27, 2013 Board meeting.

12. All agencies shall list any other matters prescribed by statute applicable to the specific agency or to any specific rule or class of rules. Additionally, an agency subject to Council review under A.R.S. §§ 41-1052 and 41-1055 shall respond to the following questions:

a. Whether the rule requires a permit, whether a general permit is used and if not, the reasons why a general permit is not used:

The rules require a permit. The Board does not issue a general permit, but issues the specific permit required under A.R.S. §§ 32-1929, 32-1930, and 32-1931.

b. Whether a federal law is applicable to the subject of the rule, whether the rule is more stringent than federal law and if so, citation to the statutory authority to exceed the requirements of federal law:

Yes, federal law is applicable for R4-23-701.04, however the rule is not more stringent than federal law. Federal requirements for automated dispensing systems are found in 21 CFR §§ 1301.17 and 1301.27.

c. Whether a person submitted an analysis to the agency that compares the rule's impact of the competitiveness of business in this state to the impact on business in other states:

No.

13. A list of any incorporated by reference material as specified in A.R.S. § 41-1028 and its location in the rule:

42 CFR 483.60, October 1, 2010 in R4-23-701(A)(4).

14. Whether the rule was previously made, amended, or repealed as an emergency rule. If so, cite the notice published in the *Register* as specified in R1-1-409(A). Also, the agency shall state where the text was changed between the emergency and the final rulemaking packages:

No.

15. The full text of the rules follows:

TITLE 4. PROFESSIONS AND OCCUPATIONS

CHAPTER 23. BOARD OF PHARMACY

ARTICLE 1. ADMINISTRATION

Section
R4-23-110. Definitions

ARTICLE 6. PERMITS AND DISTRIBUTION OF DRUGS

Section
R4-23-674. Limited-service Long-term Care Pharmacy

ARTICLE 7. NON-PHARMACY LICENSED OUTLETS - GENERAL PROVISIONS

Section
R4-23-701. Long-term Care Facilities Pharmacy Services: Consultant Pharmacist
R4-23-701.01. Long-term Care Facilities Pharmacy Services: Provider Pharmacy
R4-23-701.02. Long-term Care Facilities Pharmacy Services: Emergency Drugs
R4-23-701.04. Long-term Care Facilities Pharmacy Services: Automated Dispensing Systems
R4-23-702. Hospice Inpatient Facilities
R4-23-703. Assisted Living Facilities
R4-23-704. Customized Patient Medication Packages

ARTICLE 1. ADMINISTRATION

R4-23-110. Definitions

In addition to definitions in A.R.S. § 32-1901, the following definitions apply to 4 A.A.C. 23:

"Active ingredient" means any component that furnishes pharmacological activity or other direct effect in the diagnosis, cure, mitigation, treatment, or prevention of disease or that affects the structure or any function of the body of man or other animals. The term includes those components that may undergo chemical change in the manufacture of the drug, that are present in the finished drug product in a modified form, and that furnish the specified activity or effect.

"AHCCCS" means the Arizona Health Care Cost Containment System.

"Annual family income" means the combined yearly gross earned income and unearned income of all adult individuals within a family unit.

"Approved course in pharmacy law" means a continuing education activity that addresses practice issues related to state or federal pharmacy statutes, rules, or regulations.

"Approved Provider" means an individual, institution, organization, association, corporation, or agency that is approved by the Accreditation Council for Pharmacy Education (ACPE) in accordance with ACPE's policy and procedures or by the Board as meeting criteria indicative of the ability to provide quality continuing education.

"Assisted living facility" means a residential care institution as defined in A.R.S. § 36-401.

"Authentication of product history" means identifying the purchasing source, the ultimate fate, and any intermediate han-

dling of any component of a radiopharmaceutical or other drug.

"Automated dispensing system" means a mechanical system in a long-term care facility that performs operations or activities, other than compounding or administration, relative to the storage, packaging, counting, labeling, and dispensing of medications, and which collects, controls, and maintains all transaction information.

"Automated storage and distribution system" means a mechanical system that performs operations or activities other than counting, compounding, or administration, relative to the storage, packaging, or distributing of drugs or devices and that collects, controls, and maintains all transaction information.

"Batch" means a specific quantity of drug that has uniform character and quality, within specified limits, and is produced according to a single manufacturing order during the same cycle of manufacture.

"Beyond-use date" means:

A date determined by a pharmacist and placed on a prescription label at the time of dispensing to indicate a time beyond which the contents of the prescription are not recommended to be used; or

A date determined by a pharmacist and placed on a compounded pharmaceutical product's label at the time of preparation as specified in R4-23-410(B)(3)(d), R4-23-410(I)(6)(e), or R4-23-410(J)(1)(d) to indicate a time beyond which the compounded pharmaceutical product is not recommended to be used.

"Biological safety cabinet" means a containment unit suitable for the preparation of low to moderate risk agents when there is a need for protection of the product, personnel, and environment, consistent with National Sanitation Foundation (NSF) standards, published in the National Sanitation Foundation Standard 49, Class II (Laminar Flow) Biohazard Cabinetry, NSF International P. O. Box 130140, Ann Arbor, MI, revised June 1987 edition, (and no future amendments or editions), incorporated by reference and on file with the Board.

"Care-giver" means a person who cares for someone who is sick or disabled or an adult who cares for an infant or child and includes a patient's husband, wife, son, daughter, mother, father, sister, brother, legal guardian, nurse, or medical practitioner.

"Community pharmacy" means any place under the direct supervision of a pharmacist where the practice of pharmacy occurs or where prescription orders are compounded and dispensed other than a hospital pharmacy or a limited service pharmacy.

"Component" means any ingredient used in compounding or manufacturing drugs in dosage form, including an ingredient that may not appear in the finished product.

"Compounding and dispensing counter" means a pharmacy counter working area defined in this Section where a pharmacist or a graduate intern, pharmacy intern, pharmacy technician, or pharmacy technician trainee under the supervision of a pharmacist compounds, mixes, combines, counts, pours, or prepares and packages a prescription medication to dispense an individual prescription order or prepackages a drug for future dispensing.

"Computer system" means an automated data-processing system that uses a programmable electronic device to store, retrieve, and process data.

"Computer system audit" means an accounting method, involving multiple single-drug usage reports and audits, used to determine a computer system's ability to store, retrieve, and process original and refill prescription dispensing information.

"Contact hour" means 50 minutes of participation in a continuing education activity sponsored by an Approved Provider.

"Container" means:

A receptacle, as described in the official compendium or the federal act, that is used in manufacturing or compounding a drug or in distributing, supplying, or dispensing the finished dosage form of a drug; or

A metal receptacle designed to contain liquefied or vaporized compressed medical gas and used in manufacturing, transfilling, distributing, supplying, or dispensing a compressed medical gas.

"Continuing education" means a structured learning process required of a licensee to maintain licensure that includes study in the general areas of socio-economic and legal aspects of health care; the properties and actions of drugs and dosage forms; etiology, characteristics and therapeutics of disease status; or pharmacy practice.

"Continuing education activity" means continuing education obtained through an institute, seminar, lecture, conference, workshop, mediated instruction, programmed learning course, or postgraduate study in an accredited college or school of pharmacy.

"Continuing education unit" or "CEU" means 10 contact hours of participation in a continuing education activity sponsored by an Approved Provider.

"Continuous quality assurance program" or "CQA program" means a planned process designed by a pharmacy permittee to identify, evaluate, and prevent medication errors.

"Correctional facility" has the same meaning as in A.R.S. §§ 13-2501 and 31-341.

"CRT" means a cathode ray tube or other mechanism used to view information produced or stored by a computer system.

"CSPMP" means the Controlled Substances Prescription Monitoring Program established under A.R.S. Title 36, Chapter 28.

"Current good compounding practices" means the minimum standards for methods used in, and facilities or controls used

for, compounding a drug to ensure that the drug has the identity and strength and meets the quality and purity characteristics it is represented to possess.

"Current good manufacturing practice" means the minimum standard for methods used in, and facilities or controls used for manufacturing, processing, packing, or holding a drug to ensure that the drug meets the requirements of the federal act as to safety, and has the identity and strength and meets the quality and purity characteristics it is represented to possess.

"Cytotoxic" means a pharmaceutical that is capable of killing living cells.

"Day" means a calendar day unless otherwise specified.

"DEA" means the Drug Enforcement Administration as defined in A.R.S. § 32-1901.

"Declared disaster areas" means areas designated by the governor or by a county, city, or town under A.R.S. § 32-1910 as those areas that have been adversely affected by a natural disaster or terrorist attack and require extraordinary measures to provide adequate, safe, and effective health care for the affected population.

"Delinquent license" means a pharmacist, pharmacy intern, graduate intern, or pharmacy technician license the Board suspends for failure to renew or pay all required fees on or before the date the renewal is due.

"Dietary supplement" means a product (other than tobacco) that:

Is intended to supplement the diet that contains one or more of the following dietary ingredients: a vitamin, a mineral, an herb or other botanical, an amino acid, a dietary substance for use by man to supplement the diet by increasing the total daily intake, or a concentrate, metabolite, constituent, extract, or combinations of these ingredients;

Is intended for ingestion in pill, capsule, tablet, or liquid form;

Is not represented for use as a conventional food or as the sole item of a meal or diet;

and

Is labeled as a "dietary supplement."

"Digital signature" has the same meaning as in A.R.S. § 41-132(E).

"Dispensing pharmacist" means a pharmacist who, in the process of dispensing a prescription medication after the complete preparation of the prescription medication and before delivery of the prescription medication to a patient or patient's agent, verifies, checks, and initials the prescription medication label, as required in R4-23-402(A).

"Drug sample" means a unit of a prescription drug that a manufacturer provides free of charge to promote the sale of the drug.

"Earned income" means monetary payments received by an individual as a result of work performed or rental property owned or leased by the individual, including:

Wages,
Commissions and fees,
Salaries and tips,
Profit from self-employment,
Profit from rent received from a tenant or boarder, and
Any other monetary payments received by an individual for work performed or rental of property.

"Electronic signature" has the same meaning as in A.R.S. § 44-7002.

"Eligible patient" means a patient who a pharmacist determines is eligible to receive an immunization using professional judgment after consulting with the patient regarding the patient's current health condition, recent health condition, and allergies.

"Emergency drug supply unit" means those drugs that may be required to meet the immediate and emergency therapeutic needs of long-term care facility residents and hospice inpatient facility patients, and which are not available from any other authorized source in sufficient time to prevent risk of harm to residents or patients.

"Extreme emergency" means the occurrence of a fire, water leak, electrical failure, public disaster, or other catastrophe constituting an imminent threat of physical harm to pharmacy personnel or patrons.

"Family unit" means:

A group of individuals residing together who are related by birth, marriage, or adoption; or
An individual who:
Does not reside with another individual; or
Resides only with another individual or group of individuals to whom the individual is unrelated by birth, marriage, or adoption.

"FDA" means the Food and Drug Administration, a federal agency within the United States Department of Health and Human Services, established to set safety and quality standards for foods, drugs, cosmetics, and other consumer products.

"Health care decision maker" has the same meaning as in A.R.S. § 12-2291.

"Health care institution" has the same meaning as in A.R.S. § 36-401.

"Hospice inpatient facility" means a health care institution licensed under A.R.S. § 36-401 and Article 8 that provides hospice services to a patient requiring inpatient services.

"Immediate notice" means a required notice sent by mail, facsimile, or electronic mail to the Board Office within 24

hours.
"Immunizations training program" means an immunization training program for pharmacists, pharmacy interns, and graduate interns that meets the requirements of R4-23-411(E).
"Inactive ingredient" means any component other than an "active ingredient" present in a drug.
"Internal test assessment" means performing quality assurance or other procedures necessary to ensure the integrity of a test.
"ISO Class 5 environment" means an atmospheric environment that complies with the ISO/TC209 International Cleanroom Standards, specifically ANSI/IEST/ISO-14644-1:1999: Cleanrooms and associated controlled environments--Part 1: Classification of air cleanliness, first edition dated May 1, 1999, (and no future amendments or editions), incorporated by reference and on file in the Board office.
"ISO Class 7 environment" means an atmospheric environment that complies with the ISO/TC209 International Cleanroom Standards, specifically ANSI/IEST/ISO-14644-1:1999: Cleanrooms and associated controlled environments--Part 1: Classification of air cleanliness, first edition dated May 1, 1999, (and no future amendments or editions), incorporated by reference and on file in the Board office.
"Licensed health care professional" means an individual who is licensed and regulated under A.R.S. Title 32, Chapter 7, 11, 13, 14, 15, 16, 17, 18, 25, 29, or 35.
"Limited-service correctional pharmacy" means a limited-service pharmacy, as defined in A.R.S. § 32-1901, that:
Holds a current Board permit under A.R.S. § 32-1931;
Is located in a correctional facility; and
Uses pharmacists, interns, and support personnel to compound, produce, dispense, and distribute drugs.
"Limited-service long-term care pharmacy" means a limited-service pharmacy, as defined in A.R.S. § 32-1901, that holds a current Board-issued permit and dispenses prescription medication or prescription-only devices to patients in long-term care facilities.
"Limited-service mail-order pharmacy" means a limited-service pharmacy, as defined in A.R.S. § 32-1901, that holds a current Board permit under A.R.S. § 32-1931 and dispenses a majority of its prescription medication or prescription-only devices by mailing or delivering the prescription medication or prescription-only device to an individual by the United States mail, a common or contract carrier, or a delivery service.
"Limited-service nuclear pharmacy" means a limited-service pharmacy, as defined in A.R.S. § 32-1901, that holds a current Board permit under A.R.S. § 32-1931 and provides radiopharmaceutical services.
"Limited-service pharmacy permittee" means a person who holds a current limited-service pharmacy permit in compliance with A.R.S. §§ 32-1929, 32-1930, 32-1931, and A.A.C. R4-23-606.
"Limited-service sterile pharmaceutical products pharmacy" means a limited-service pharmacy, as defined in A.R.S. § 32-1901, that holds a current Board permit under A.R.S. § 32-1931 and dispenses a majority of its prescription medication or prescription-only devices as sterile pharmaceutical products.
"Long-term care consultant pharmacist" means a pharmacist providing consulting services to a long-term care facility.
"Long-term care facility" or "LTCF" means a nursing care institution as defined in A.R.S. § 36-401 ~~or an assisted living facility that:~~
~~Provides 24-hour, seven-day a week licensed nursing services to resident patients; and~~
~~Is licensed by the Arizona Department of Health Services~~.
"Lot" means a batch or any portion of a batch of a drug, or if a drug produced by a continuous process, an amount of drug produced in a unit of time or quantity in a manner that assures its uniformity. In either case, a lot is identified by a distinctive lot number and has uniform character and quality with specified limits.
"Lot number" or "control number" means any distinctive combination of letters or numbers, or both, from which the complete history of the compounding or manufacturing, control, packaging, and distribution of a batch or lot of a drug can be determined.
"Low-income subsidy" means Medicare-provided assistance that may partially or fully cover the costs of drugs and is based on the income of an individual and, if applicable, the individual's spouse.
"Materials approval unit" means any organizational element having the authority and responsibility to approve or reject components, in-process materials, packaging components, and final products.
"Mechanical counting device for a drug in solid, oral dosage form" means a mechanical device that counts drugs in solid, oral dosage forms for dispensing and includes an electronic balance when used to count drugs.
"Mechanical storage and counting device for a drug in solid, oral dosage form" means a mechanical device that stores and counts and may package or label drugs in solid, oral dosage forms for dispensing.
"Mediated instruction" means information transmitted via intermediate mechanisms such as audio or video tape or telephone transmission.
"Medical practitioner-patient relationship" means that before prescribing, dispensing, or administering a prescription-only drug, prescription-only device, or controlled substance to a person, a medical practitioner, as defined in A.R.S. § 32-1901, shall first conduct a physical examination of that person or have previously conducted a physical examination.
This subdivision does not apply to:

A medical practitioner who provides temporary patient supervision on behalf of the patient's regular treating medical practitioner;
Emergency medical situations as defined in A.R.S. § 41-1831;
Prescriptions written to prepare a patient for a medical examination; or
Prescriptions written, prescription-only drugs, prescription-only devices, or controlled substances issued for use by a county or tribal public health department for immunization programs, emergency treatment, in response to an infectious disease investigation, public health emergency, infectious disease outbreak or act of bioterrorism. For purposes of this subsection, "bioterrorism" has the same meaning as in A.R.S. § 36-781.

"Medicare" means a federal health insurance program established under Title XVIII of the Social Security Act.
"Medication error" means any unintended variation from a prescription or medication order. Medication error does not include any variation that is corrected before the medication is dispensed to the patient or patient's care-giver, or any variation allowed by law.
"Mobile pharmacy" means a pharmacy that is self propelled or movable by another vehicle that is self propelled.
"MPJE" means Multistate Pharmacy Jurisprudence Examination, a Board-approved national pharmacy law examination written and administered in cooperation with NABP.
"NABP" means National Association of Boards of Pharmacy.
"NABPLEX" means National Association of Boards of Pharmacy Licensure Examination.
"NAPLEX" means North American Pharmacist Licensure Examination.
"Order" means either of the following:
A prescription order as defined in A.R.S. § 32-1901; or
A medication order as defined in A.A.C. R4-23-651.
"Other designated personnel" means a non-pharmacist individual who is permitted in the pharmacy area, for a limited time, under the direct supervision of a pharmacist, to perform non-pharmacy related duties, such as trash removal, floor maintenance, and telephone or computer repair.
"Outpatient" means an individual who is not a residential patient in a health care institution.
"Outpatient setting" means a location that provides medical treatment to an outpatient.
"Patient profile" means a readily retrievable, centrally located information record that contains patient demographics, allergies, and medication profile.
"Pharmaceutical patient care services" means the provision of drug selection, drug utilization review, drug administration, drug therapy monitoring, and other drug-related patient care services intended to achieve outcomes related to curing or preventing a disease, eliminating or reducing a patient's symptoms, or arresting or slowing a disease process, by identifying and resolving or preventing potential and actual drug-related problems.
"Pharmaceutical product" means a medicinal drug.
"Pharmacy counter working area" means a clear and continuous working area that contains no major obstacles such as a desktop computer, computer monitor, computer keyboard, external computer drive device, printer, facsimile machine, pharmacy balance, typewriter, or pill-counting machine, but may contain individual documents or prescription labels, pens, prescription blanks, refill log, pill-counting tray, spatula, stapler, or other similar items necessary for the prescription-filling process.
"Pharmacy law continuing education" means a continuing education activity that addresses practice issues related to state or federal pharmacy statutes, rules, or regulations, offered by an Approved Provider.
"Pharmacy permittee" means a person who holds a current pharmacy permit that complies with A.R.S. §§ 32-1929, 32-1930, 32-1931, 32-1934, and A.A.C. R4-23-606 and R4-23-652.
"Physician" means a medical practitioner licensed under A.R.S. Title 32, Chapter 13 or 17.
"Physician-in-charge" means a physician who is responsible to the Board for all aspects of a prescription medication donation program required in A.R.S. § 32-1909 and operated in the physician's office or in a health care institution.
"Poverty level" means the annual family income for a family unit of a particular size, as specified in the poverty guidelines updated annually in the Federal Register by the U.S. Department of Health and Human Services.
"Precursor chemical" means a precursor chemical I as defined in A.R.S. § 13-3401(26) and a precursor chemical II as defined in A.R.S. § 13-3401(27).
"Prepackaged drug" means a drug that is packaged in a frequently prescribed quantity, labeled in compliance with A.R.S. §§ 32-1967 and 32-1968, stored, and subsequently dispensed by a pharmacist or a graduate intern or pharmacy intern under the supervision of a pharmacist, who verifies at the time of dispensing that the drug container is properly labeled, in compliance with A.R.S. § 32-1968, for the patient.
"Prep area" means a specified area either within an ISO class 7 environment or adjacent to but outside an ISO class 7 environment that:
Allows the assembling of necessary drugs, supplies, and equipment for compounding sterile pharmaceutical products, but does not allow the use of paper products such as boxes or bulk drug storage;
Allows personnel to don personnel protective clothing, such as gown, gloves, head cover, and booties before entering the clean compounding area; and

Is a room or a specified area within a room, such as an area specified by a line on the floor.

"Primary care provider" means the medical practitioner who is treating an individual for a disease or medical condition.

"Proprietor" means the owner of a business permitted by the Board under A.R.S. §§ 32-1929, 32-1930, 32-1931, and 32-1934.

"Provider pharmacy" means a pharmacy that contracts with a long-term care facility to supply prescription medication or other services for residents of a long-term care facility.

"Radiopharmaceutical" means any drug that emits ionizing radiation and includes:

Any nonradioactive reagent kit, nuclide generator, or ancillary drug intended to be used in the preparation of a radiopharmaceutical, but does not include drugs such as carbon-containing compounds or potassium-containing salts, that contain trace quantities of naturally occurring radionuclides; and

Any biological product that is labeled with a radionuclide or intended to be labeled with a radionuclide.

"Radiopharmaceutical quality assurance" means performing and interpreting appropriate chemical, biological, and physical tests on radiopharmaceuticals to determine the suitability of the radiopharmaceutical for use in humans and animals. Radiopharmaceutical quality assurance includes internal test assessment, authentication of product history, and appropriate record retention.

"Radiopharmaceutical services" means procuring, storing, handling, compounding, preparing, labeling, quality assurance testing, dispensing, distributing, transferring, recordkeeping, and disposing of radiochemicals, radiopharmaceuticals, and ancillary drugs.

Radiopharmaceutical services include quality assurance procedures, radiological health and safety procedures, consulting activities associated with the use of radiopharmaceuticals, and any other activities required for the provision of pharmaceutical care.

"Red C stamp" means a device used with red ink to imprint an invoice with a red letter C at least one inch high, to make an invoice of a Schedule III through IV controlled substance, as defined in A.R.S. § 36-2501, readily retrievable, as required by state and federal rules.

"Refill" means other than the original dispensing of the prescription order, dispensing a prescription order in the same quantity originally ordered or in multiples of the originally ordered quantity when specifically authorized by the prescriber, if the refill is authorized by the prescriber:

In the original prescription order;

By an electronically transmitted refill order that the pharmacist promptly documents and files; or

By an oral refill order that the pharmacist promptly documents and files.

"Regulated chemical" means the same as in A.R.S. § 13-3401(30).

"Remodel" means to alter structurally the pharmacy area or location.

"Remote drug storage area" means an area that is outside the premises of the pharmacy, used for the storage of drugs, locked to deny access by unauthorized persons, and secured against the use of force.

"Resident" means:

An individual admitted to and living in a long-term care facility or an assisted living facility,

An individual who has a place of habitation in Arizona and lives in Arizona as other than a tourist, or

A person who owns or operates a place of business in Arizona.

"Responsible person" means the owner, manager, or other employee who is responsible to the Board for a permitted establishment's compliance with the laws and administrative rules of this state and of the federal government pertaining to distribution of drugs, devices, precursor chemicals, and regulated chemicals. Nothing in this definition relieves other individuals from the responsibility to comply with state and federal laws and administrative rules.

"Score transfer" means the process that enables an applicant to take the NAPLEX in a jurisdiction and be eligible for licensure by examination in other jurisdictions.

"Security features" means the attributes incorporated into the paper of a prescription order, referenced in A.R.S. § 32-1968(A)(4), that are approved by the Board or its staff and that includes one or more of the following features that attempt to prevent duplication or aid the authentication of a paper document: laid lines, enhanced laid lines, thermochromic ink, artificial watermark, fluorescent ink, chemical void, persistent void, penetrating numbers, high-resolution border, high-resolution latent images, micro-printing, prismatic printing, embossed images, abrasion ink, holograms, and foil stamping.

"Shared order filling" means the following:

Preparing, packaging, compounding, or labeling an order, or any combination of these functions, that are performed by:

A person with a current Arizona Board license, located at an Arizona pharmacy, on behalf of and at the request of another resident or nonresident pharmacy; or

A person, located at a nonresident pharmacy, on behalf of and at the request of an Arizona pharmacy; and

Returning the filled order to the requesting pharmacy for delivery to the patient or patient's care-giver or, at the request of this pharmacy, directly delivering the filled order to the patient.

"Shared order processing" means the following:

Interpreting the order, performing order entry verification, drug utilization review, drug compatibility and drug

allergy review, final order verification, and when necessary, therapeutic intervention, or any combination of these order processing functions, that are performed by:

A pharmacist or intern, under pharmacist supervision, with a current Arizona Board license, located at an Arizona pharmacy, on behalf of and at the request of another resident or nonresident pharmacy: or

A pharmacist or intern, under pharmacist supervision, located at a nonresident pharmacy, on behalf of and at the request of an Arizona pharmacy; and

After order processing is completed, returning the processed order to the requesting pharmacy for order filling and delivery to the patient or patient's care-giver or, at the request of this pharmacy, returning the processed order to another pharmacy for order filling and delivery to the patient or patient's care-giver.

"Shared services" means shared order filling or shared order processing, or both.

"Sight-readable" means that an authorized individual is able to examine a record and read its information from a CRT, microfiche, microfilm, printout, or other method acceptable to the Board or its designee.

"Single-drug audit" means an accounting method that determines the numerical and percentage difference between a drug's beginning inventory plus purchases and ending inventory plus sales.

"Single-drug usage report" means a computer system printout of original and refill prescription order usage information for a single drug.

"Standard-risk sterile pharmaceutical product" means a sterile pharmaceutical product compounded from sterile commercial drugs using sterile commercial devices or a sterile pharmaceutical otic or ophthalmic product compounded from non-sterile ingredients.

"State of emergency" means a governmental declaration issued under A.R.S. § 32-1910 as a result of a natural disaster or terrorist attack that results in individuals being unable to refill existing prescriptions.

"Sterile pharmaceutical product" means a medicinal drug free from living biological organisms.

"Strength" means:

The concentration of the drug substance (for example, weight/weight, weight/volume, or unit dose/volume basis); or

The potency, that is, the therapeutic activity of a drug substance as indicated by bioavailability tests or by controlled clinical data (expressed, for example, in terms of unity by reference to a standard).

"Substantial-risk sterile pharmaceutical product" means a sterile pharmaceutical product compounded as a parenteral or injectable dosage form from non-sterile ingredients.

"Supervision" means a pharmacist is present, assumes legal responsibility, and has direct oversight of activities relating to acquiring, preparing, distributing, and selling prescription medications by pharmacy interns, graduate interns, pharmacy technicians, or pharmacy technician trainees and when used in connection with the intern training requirements means that, in a pharmacy where intern training occurs, a pharmacy intern preceptor assumes the primary responsibility of teaching the intern during the entire period of the training.

"Supplying" means selling, transferring, or delivering to a patient or a patient's agent one or more doses of:

A nonprescription drug in the manufacturer's original container for subsequent use by the patient, or

A compressed medical gas in the manufacturer's or compressed medical gas distributor's original container for subsequent use by the patient.

"Support personnel" means an individual, working under the supervision of a pharmacist, trained to perform clerical duties associated with the practice of pharmacy, including cashiering, bookkeeping, pricing, stocking, delivering, answering non-professional telephone inquiries, and documenting third-party reimbursement. Support personnel shall not perform the tasks of a pharmacist, pharmacy intern, graduate intern, pharmacy technician, or pharmacy technician trainee.

"Temporary pharmacy facility" means a facility established as a result of a declared state of emergency to temporarily provide pharmacy services within or adjacent to declared disaster areas.

"Tourist" means an individual who is living in Arizona but maintains a place of habitation outside of Arizona and lives outside of Arizona for more than six months during a calendar year.

"Transfill" means a manufacturing process by which one or more compressed medical gases are transferred from a bulk container to a properly labeled container for subsequent distribution or supply.

"Unearned income" means monetary payment received by an individual that is not compensation for work performed or rental of property owned or leased by the individual, including:

Unemployment insurance,
Workers' compensation,
Disability payments,
Payments from the Social Security Administration,
Payments from public assistance,
Periodic insurance or annuity payments,
Retirement or pension payments,
Strike benefits from union funds,
Training stipends,

Child support payments,
Alimony payments,
Military family allotments,
Regular support payments from a relative or other individual not residing in the household,
Investment income,
Royalty payments,
Periodic payments from estates or trusts, and
Any other monetary payments received by an individual that are not:
As a result of work performed or rental of property owned by the individual,
Gifts,
Lump-sum capital gains payments,
Lump-sum inheritance payments,
Lump-sum insurance payments, or
Payments made to compensate for personal injury.

"Verified signature" or "signature verifying" means in relation to a Board license or permit application or report, form, or agreement, the hand-written or electronic signature of an individual who, by placing a hand-written or electronic signature on a hard-copy or electronic license or permit application or report, form, or agreement agrees with and verifies that the statements and information within or attached to the license or permit application or report, form, or agreement are true in every respect and that inaccurate reporting can result in denial or loss of a license or permit or report, form, or agreement.
"Veteran" means an individual who has served in the United States Armed Forces.
"Wholesale distribution" means distribution of a drug to a person other than a consumer or patient, but does not include:
Selling, purchasing, or trading a drug or offering to sell, purchase, or trade a drug for emergency medical reasons. For purposes of this Section, "emergency medical reasons" includes transferring a prescription drug by a community or hospital pharmacy to another community or hospital pharmacy to alleviate a temporary shortage;
Selling, purchasing, or trading a drug, offering to sell, purchase, or trade a drug, or dispensing a drug as specified in a prescription;
Distributing a drug sample by a manufacturers' or distributors' representative; or
Selling, purchasing, or trading blood or blood components intended for transfusion.
"Wholesale distributor" means any person engaged in wholesale distribution of drugs, including: manufacturers; repackers; own-label distributors; private-label distributors; jobbers; brokers; warehouses, including manufacturers' and distributors' warehouses, chain drug warehouses, and wholesale drug warehouses; independent wholesale drug traders; and retail pharmacies that conduct wholesale distributions in the amount of at least 5% of gross sales.

ARTICLE 6. PERMITS AND DISTRIBUTION OF DRUGS

R4-23-674. Limited-service Long-term Care Pharmacy

A. A limited-service pharmacy permittee shall ensure that the limited-service long-term care pharmacy complies with:
1. The general requirements of R4-23-671;
2. The professional practice standards of Article 4 and Article 11; and
3. The permits and drug distribution standards of R4-23-606 through R4-23-612, R4-23-670, and this Section.

B. If a limited-service long-term care pharmacy permittee contracts with a long-term care facility as a Provider Pharmacy, as defined in R4-23-110, the limited-service long-term care pharmacy permittee shall ensure that~~:~~
~~1. The limited-service long-term care pharmacy employs or contracts with a long-term care consultant pharmacist; and~~
~~2.~~ ~~The~~ the long-term care consultant pharmacist and the pharmacist-in-charge of the limited-service long-term care pharmacy comply with R4-23-701, R4-23-701.01, R4-23-701.02, ~~and~~ R4-23-701.03, R4-23-701.04, and this Section.

C. The limited-service long-term care pharmacy permittee or pharmacist-in-charge shall ensure that prescription medication is delivered to the patient's long-term care facility or locked in the dispensing area of the pharmacy when a pharmacist is not present in the pharmacy.

D. The pharmacist-in-charge of a limited-service long-term care pharmacy shall authorize only those individuals listed in R4-23-610(B) to be in the limited-service long-term care pharmacy.

E. In consultation with the long-term care facility's medical director and director of nursing, the long-term care consultant pharmacist and pharmacist-in-charge of the long-term care facility's provider pharmacy may develop, if necessary, a medication formulary for the long-term care facility that ensures the safe and efficient procurement, dispensing, distribution, administration, and control of drugs in the long-term care facility.

F. The limited-service long-term care pharmacy permittee or pharmacist-in-charge shall ensure that the written policies and procedures required in R4-23-671(E) include the following:
1. Clinical services and drug utilization management for:
   a. Drug utilization reviews,
   b. Inventory audits,
   c. Patient outcome monitoring,

d. Drug information, and
e. Education of pharmacy and other health professionals;
2. Controlled substances;
3. Drug compounding, dispensing, and storage;
4. Drug delivery requirements for:
a. Transportation,
b. Security,
c. Temperature and other environmental controls, and
d. Emergency provisions;
5. Drug product procurement;
6. Duties and qualifications of professional and support staff;
7. Emergency drug supply unit procedures;
8. Formulary, including development, review, modification, use, and documentation, if applicable;
9. Patient profiles;
10. Patient education;
11. Prescription orders~~:~~, including:
a. Approved abbreviations,
b. Stop-order procedures, and
c. Leave-of-absence and discharge prescription order procedures;
12. Quality management procedures for:
a. Adverse drug reactions,
b. Drug recalls,
c. Expired and beyond-use-date drugs,
d. Medication or dispensing errors, and
e. Education of professional and support staff;
13. Recordkeeping;
14. Sanitation; and
15. Security.

ARTICLE 7. NON-PHARMACY LICENSED OUTLETS - GENERAL PROVISIONS

R4-23-701. Long-term Care Facilities Pharmacy Services: Consultant Pharmacist

A. The long-term care consultant pharmacist as defined in R4-23-110~~, in cooperation with the pharmacist-in-charge of a provider pharmacy~~ shall:

1. ~~Prepare, implement, review, and revise in the same manner described in R4-23-671(E) and comply with written policies and procedures for the safe and efficient receipt, distribution, and storage of pharmaceutical products by the long-term care facility;~~ Possess a valid Arizona pharmacist license issued by the Board;
2. ~~Make the policies and procedures available in the provider pharmacy and long-term care facility for employee reference and inspection by the Board or its designee; and~~ Ensure the provision of pharmaceutical patient care services as defined in R4-23-110;
3. ~~Ensure that the written policies and procedures required under (A)(1) include the following:~~ Review the distribution and storage of drugs and devices and assist the facility in establishing policies and procedures for the distribution and storage of drugs and devices;
~~a. Specification for the storage, distribution, and procurement of drugs and biologicals;~~
~~b. Resident evaluation programs that relate to monitoring the therapeutic response and use of all drugs and biologicals prescribed or administered to residents, using as guidelines the most current indicators established by the Centers for Medicare and Medicaid Services, United States Department of Health and Human Services as required in 42 CFR 483.60, published October 1, 2001, and no future amendments or editions, incorporated by reference and on file with the Board and the Office of the Secretary of State.~~
~~c. Pharmacist assistance in drug-related emergency situations on a 24-hour basis;~~
~~d. Controlled substance accountability including:~~
~~i. Date and time of administration,~~
~~ii. Name of the person who administers the controlled substance,~~
~~iii. Documenting and verifying of any wasted or partial doses, and~~
~~iv. Exception reports for refused doses;~~
~~e. Prescription order requirements;~~
~~f. Approved abbreviations;~~
~~g. Stop-order procedures;~~
~~h. Pass and discharge prescription order procedures;~~
~~i. Emergency drug supply unit procedures;~~

~~j. Formulary procedures, including development, review, modification, use, and documentation, if applicable;~~
~~k. Security and temperature control procedures for all drugs and biologicals;~~
~~l. Disposal procedures that comply with subsection (D) for discontinued or outdated, prescription-only drugs or containers with illegible or missing labels; and~~
~~m. Procedures for identifying and reporting to proper authorities drug irregularities and dispensing errors.~~

4. Provide resident evaluation programs that relate to monitoring the therapeutic response and utilization of all drugs and devices prescribed or administered to residents, using as guidelines the most current indicators established by the Centers for Medicare and Medicaid Services, United States Department of Health and Human Services as required in 42 CFR 483.60 (revised October 1, 2010, incorporated by reference and on file with the Board. This incorporated material contains no future editions or amendments.).
5. Serve as a resource for pharmacy-related education services within the facility;
6. Participate in quality management of resident care in the facility; and
7. Communicate with the provider pharmacy regarding areas of mutual concern and resolution.

B. A long-term care consultant pharmacist shall ensure that:

~~1. A pharmacist evaluates and verifies a prescription order of a long-term care facility resident in compliance with R4-23-402(A)(5) and (6);~~
~~2. The prescription order of a long-term care facility resident contains:~~
~~a. Resident's name;~~
~~b. Facility name or address;~~
~~c. Drug name, strength, and dosage form;~~
~~d. Directions for use;~~
~~e. Date issued; and~~
~~f. Name of prescriber;~~

~~3.~~1. When a provider pharmacy is not open for business, arrangements are made in advance by the long-term care consultant pharmacist, in cooperation with the pharmacist-in-charge of the provider pharmacy and the director of nursing and medical staff of the long-term care facility, for providing emergency drugs for the licensed nursing staff to administer to the residents of the facility using an emergency drug supply unit located at the facility;
~~4.~~2. The label and packaging of prescription-only and nonprescription drugs intended for use within a long-term care facility complies with ~~R4-23-701.01 and~~ state and federal law; and
~~5.~~3. ~~A long-term care facility's personnel is informed that laws governing controlled substances require that a long-term care facility:~~ The long-term care facility:
a. ~~Store~~ Stores controlled substances listed in A.R.S. § 36-2513 in a separately locked and permanently affixed compartment, unless the facility uses a single-unit package medication distribution system~~,~~; and
b. ~~Maintain~~ Maintains accurate records of controlled substance administration or ultimate disposition.

C. The long-term care consultant pharmacist shall:
1. ~~ensure~~ Ensure availability of records and reports designed to provide the data necessary to evaluate the drug use of each long-term care facility resident that include the following:
~~1.~~a. Provider pharmacy patient profiles and long-term care facility medication administration records;
~~2.~~b. Reports of suspected adverse drug reactions;
~~3.~~c. Inspection reports of drug storage areas with emphasis on detecting outdated drugs; and
~~4.~~d. Accountability reports, ~~including all drug destruction forms.~~ that include:
i. Date and time of administration,
ii. Name of the person who administered the drug,
iii. Documentation and verification of any wasted or partial doses,
iv. Exception reports for refused doses, and
v. All drug destruction forms; and
2. Identify and report drug irregularities and dispensing errors to the prescriber, the director of nursing of the facility, and the provider pharmacy.

D. A long-term care consultant pharmacist or pharmacist-in-charge of a provider pharmacy shall ensure that:
1. Discontinued or outdated drugs, including controlled substances, are destroyed or disposed of~~:~~
~~a. Under the supervision of either a long-term care consultant pharmacist or a pharmacist employed by a provider pharmacy and witnessed by the long-term care facility administrator or the administrator's designee;~~
~~b. List by drug name, strength, dosage form, and quantity; and~~
~~c. In~~ in a timely manner using methods consistent with federal, state, and local requirements and subject to review by the Board or its ~~designee~~ staff; and
2. Drug containers with illegible or missing labels are:
a. Identified; and
b. Replaced or relabeled by a pharmacist employed by the pharmacy that dispensed the prescription medication.

R4-23-701.01. Long-term Care Facilities Pharmacy Services: Provider Pharmacy

The limited-service pharmacy permittee or pharmacist-in-charge of a provider pharmacy shall ensure that:

1. A prescription medication is provided only by a valid prescription order for an individual long-term care facility resident, properly labeled for that resident, as specified in this subsection. Nothing in this Section shall prevent a provider pharmacy from supplying nonprescription drugs in a manufacturer's unopened container or emergency drugs using an emergency drug supply unit as specified in R4-23-701.02;
2. A prescription medication label for a long-term care facility resident complies with A.R.S. §§ ~~32-1963.01(C) and (I),~~ 32-1968~~,~~ and 36-2525 ~~and the applicable parts of R4-23-658(D),~~ and contains:
   a. The drug name, strength, dosage form, and quantity; and
   b. The beyond-use-date;
3. Only a pharmacist employed by the pharmacy that dispensed the prescription medication may, through the exercise of professional ~~judgement~~ judgment, relabel or alter a prescription medication label that is illegible or missing;
4. The ~~long-term care facility~~ provider pharmacy develops and implements drug recall policies and procedures that protect the health and safety of facility residents. The drug recall procedures shall include immediate discontinuation of any patient level recalled drug and notification of the prescriber and director of nursing of the facility;~~-~~and
5. ~~The provider pharmacy or any of its employees does not pay any rebate under A.R.S. § 32-1932(D) and R4-23-404.~~ Drugs previously dispensed to a resident of the long-term care facility by another pharmacy, and drugs previously dispensed by the provider pharmacy, are not repackaged.

R4-23-701.02. Long-term Care Facilities Pharmacy Services: Emergency Drugs

A. The limited-service pharmacy permittee or pharmacist-in-charge of a provider pharmacy shall ensure that:
   1. ~~an~~ An emergency drug supply unit is available within the long-term care facility~~.~~.
   2. Drugs contained in an emergency drug supply unit remain the property of the provider pharmacy, and
   3. Controlled substance drugs contained in an emergency drug supply unit are included in all inventories required under A.R.S. § 36-2523(B) and R4-23-1003(A).

B. An emergency drug supply unit shall ~~contain only a drug that meets~~ meet the following criteria:
   1. The ~~drug is~~ drugs are necessary to meet the ~~emergent and immediate~~ immediate and emergency therapeutic needs of long-term care facility residents as determined by the provider pharmacy's pharmacist-in-charge in consultation with the long-term care facility's medical director and nursing director; ~~and~~
   2. The purpose of the emergency drug supply unit in a long-term care facility is not to relieve a provider pharmacy of the responsibility for timely provision of the resident's routine drug needs, but to ensure that an emergency drug supply unit is available for facility residents in need of immediate and emergency therapeutic drugs; and
   ~~2.~~3. The ~~drug is packaged~~ drugs are provided in a manufacturer's unit of use package or are prepackaged and labeled to include the drug name, strength, dosage form, manufacturer, lot number, and expiration date and provider pharmacy's name, address, telephone number, and pharmacist's initials.

C. The limited-service pharmacy permittee or pharmacist-in-charge of a provider pharmacy shall ensure that an emergency drug supply unit:
   1. Is stored in an area that:
      a. Is temperature controlled; and
      b. Prevents unauthorized access;
   2. Contains on the exterior of the emergency drug supply unit a label to indicate that the contents are for emergency use only;
   3. Contains on the exterior of the emergency drug supply unit a complete list of the contents of the unit by drug name, strength, dosage form, ~~expiration date~~, and quantity and the provider pharmacy's name, address, and telephone number; ~~and~~
   4. Contains on the exterior of the emergency drug supply unit a label that indicates the date of the earliest drug expiration date; and
   ~~4.~~5. Contains on the exterior of the emergency drug supply unit a label that indicates the date of and ~~person~~ pharmacist responsible for the last inspection of the emergency drug supply unit~~.~~; and
   6. Is secured with a tamper-evident seal, or is locked and sealed in a manner that obviously reveals when the unit has been opened or tampered with.

D. The limited-service pharmacy permittee or pharmacist-in-charge of a provider pharmacy shall:
   1. Prepare, implement, review, and revise in the same manner described in R4-23-671(E) and comply with written policies and procedures for the storage and use of an emergency drug supply unit in a long-term care facility;
   2. Make the policies and procedures available in the provider pharmacy and long-term care facility for employee reference and inspection by the Board or its ~~designee~~ staff; ~~and~~
   3. Ensure that the written policies and procedures include the following:
      a. Drug removal procedures that require~~s~~:
         i. The long-term care facility's personnel receive a valid prescription order for each drug removed from the emergency drug supply unit,
         ii. The long-term care facility's personnel notify the provider pharmacy when a drug is removed from the emer-

gency drug supply unit, ~~and~~

~~iii. The provider pharmacy's personnel restock the emergency drug supply unit within 48 hours of receiving the notification required in subsection (D)(3)(a)(ii),~~

b. Outdated drug replacement procedures ~~that requires:~~, and

~~i. The provider pharmacy's personnel check for outdated drugs in the emergency drug supply unit once a month,~~

~~ii. The long-term care facility's personnel notify the provider pharmacy when an outdated drug is found in the emergency drug supply unit,~~

~~iii. The provider pharmacy's personnel remove an outdated drug from the emergency drug supply unit within 48 hours~~ seven days ~~of receiving the notification required in subsection (D)(3)(b)(ii), and~~

~~iv. The provider pharmacy's personnel restock the emergency drug supply unit within 48 hours of receiving the notification required in subsection (D)(3)(b)(ii), and~~

c. Security and inspection procedures; ~~and~~

4. Exchange or restock the emergency drug supply unit weekly, or more often as necessary, to ensure the availability of an adequate supply of emergency drugs within the long-term care facility. Restocking of the emergency drug supply unit at the facility shall be completed by an Arizona licensed pharmacist employed by the provider pharmacy, or by an Arizona licensed intern, graduate intern, technician or technician trainee under the direct onsite supervision of an Arizona licensed pharmacist; and

~~4.~~5. Educate pharmacy and long-term care facility personnel in the storage and use of an emergency drug supply unit.

E. In addition to the requirements of subsections (A) through (D), an automated emergency drug supply unit may be used provided:

1. The pharmacy permittee or pharmacist-in-charge of the provider pharmacy notifies the Board or its staff in writing of the intent to use an automated emergency drug supply unit, including the name and type of unit;
2. The provider pharmacy is notified electronically when the automated emergency drug supply unit has been accessed;
3. All events involving the access of the automated emergency drug supply unit are recorded electronically and maintained for not less than two years;
4. The provider pharmacy is capable of producing a report of all transactions of the automated emergency drug supply unit including a single drug usage report as required in R4-23-408(B)(5) on inspection by the Board or its staff;
5. The provider pharmacy develops written policies and procedures for:
   a. Accessing the automated emergency drug supply unit in the event of a system malfunction or downtime,
   b. Authorizing and modifying user access,
   c. An ongoing quality assurance program that includes:
      i. Training in the use of the automated emergency drug supply unit for all authorized users,
      ii. Maintenance and calibration of the automated emergency drug supply unit as recommended by the device manufacturer; and
6. Documentation of the requirements of subsection (E)(5)(c)(ii) is maintained for inspection by the Board or its staff for not less than two years.

F. The Board may prohibit a pharmacy permittee or pharmacist-in-charge of a provider pharmacy from using an automated emergency drug supply unit if the pharmacy permittee or pharmacy permittee's employees do not comply with the requirements of subsections (A) through (E).

R4-23-701.04. Long-term Care Facilities Pharmacy Services: Automated Dispensing Systems

A. Before using an automated dispensing system as defined in R4-23-110, a pharmacy permittee or pharmacist-in-charge of a provider pharmacy shall:

1. Notify the Board or its staff in writing of the intent to use an automated dispensing system, including the name and type of system;
2. Obtain a separate controlled substances registration at the location of each long-term care facility at which an automated dispensing system containing controlled substances will be located as required by federal law; and
3. Maintain copies of the registrations required under subsection (A)(2) at the provider pharmacy for inspection by the Board or its staff.

B. A pharmacy permittee or pharmacist-in-charge of a provider pharmacy shall ensure:

1. Drugs contained in an automated dispensing system remain the property of the provider pharmacy,
2. Controlled substance drugs contained in an automated dispensing system are included in all inventories required under A.R.S. § 36-2523(B) and R4-23-1003(A),
3. Schedule II drugs are not stocked in an automated dispensing system, and
4. A separate emergency drug supply unit is available in the long-term care facility to meet the requirements of R4-23-701.02.

C. A pharmacy permittee or pharmacist-in-charge of a provider pharmacy shall:

1. Ensure that policies and procedures as required in subsection (D) for the use of an automated dispensing system in a long-term care facility are prepared, implemented, and complied with;

2. Review biennially and, if necessary, revise the policies and procedures required under subsection (D);
3. Document the review required under subsection (C)(2);
4. Assemble the policies and procedures as a written or electronic manual; and
5. Make the policies and procedures available for employee reference and inspection by the Board or its staff within the pharmacy and at any location outside of the pharmacy where the automated dispensing system is used.

D. A pharmacy permittee or pharmacist-in-charge of a provider pharmacy shall ensure the written policies and procedures include:

1. Drug removal procedures that include the following:
   a. A drug is provided only by a valid prescription order for an individual long-term care facility resident;
   b. A drug is dispensed from an automated dispensing system only after a pharmacist has:
      i. Reviewed and verified the resident's prescription order as required by R4-23-402(A), and
      ii. Electronically authorized the access for that drug for that particular resident, and
   c. The automated dispensing system labels each individual drug packet with a resident specific label that complies with R4-23-701.01(2) and contains the resident's room number or facility identification number; and
2. Security procedures that include the following:
   a. The pharmacy permittee or pharmacist-in-charge of the provider pharmacy is responsible for authorizing user access, including adding and removing users and modifying user access;
   b. Each authorized user is a licensee of the Board or authorized licensed personnel of the long-term care facility; and
   c. The automated dispensing system is secured at the long-term care facility by electronic or mechanical means or a combination thereof designed to prevent unauthorized access;
3. Drug stocking procedures that include the following:
   a. Automated dispensing systems that use non-removable containers that do not allow prepackaging of the container as set out in subsection (D)(3)(b):
      i. Are stocked at the long-term care facility by an Arizona licensed pharmacist employed by the provider pharmacy, or by an Arizona licensed intern, graduate intern, technician or technician trainee under the direct onsite supervision of an Arizona licensed pharmacist; and
      ii. Utilize bar code or other technologies to ensure the correct drug is placed in the correct canister or container; and
   b. Automated dispensing systems that use removable containers may be stocked at the long-term care facility by an authorized user provided:
      i. The prepackaging of the container occurs at the provider pharmacy;
      ii. A pharmacist verifies the container has been properly filled and labeled, and the container is secured with a tamper-evident seal;
      iii. The individual containers are transported to the long-term care facility in a secure, tamper-evident shipping container; and
      iv. The automated dispensing system uses microchip, bar-coding, or other technologies to ensure the containers are accurately loaded in the automated dispensing system; and
4. Recordkeeping and report procedures that include the following:
   a. All events involving the access of the automated dispensing system are recorded electronically and maintained for not less than two years;
   b. The provider pharmacy is capable of producing a report of all transactions of the automated dispensing system including:
      i. A single drug usage report that complies with R4-23-408(B)(5); and
      ii. An authorized user history including date and time of access and type of transaction; and
   c. The provider pharmacy has procedures to safeguard the storage, packaging, and distribution of drugs by monitoring:
      i. Current inventory;
      ii. Expiration dates;
      iii. Controlled substance dispensing;
      iv. Re-dispense requests; and
      v. Wastage.

E. A pharmacy permittee or pharmacist-in-charge of a provider pharmacy shall:

1. Ensure that an electronic log is kept for each container fill that includes:
   a. An identification of the container by drug name and strength, and container number;
   b. The drug's manufacturer or National Drug Code (NDC) number;
   c. The expiration date and lot number from the manufacturer's stock bottle that is used to fill the container. If multiple lot numbers of the same drug are added to a container, each lot number and expiration date shall be documented;

d. The date the container is filled;
e. Documentation of the identity of the licensee who placed the drug into the container; and
f. If the licensee who filled the container is not a pharmacist, documentation of the identity of the pharmacist who supervised the non-pharmacist licensee; and

2. Maintain the electronic log for inspection by the Board or its staff for not less than two years.

F. A pharmacy permittee or pharmacist-in-charge of a provider pharmacy shall:

1. Implement an ongoing quality assurance program that monitors performance of the automated dispensing system and compliance with the established policies and procedures that includes:
   a. Training in the use of the automated dispensing system for all authorized users,
   b. Maintenance and calibration of the automated dispensing system as recommended by the device manufacturer,
   c. Routine accuracy validation testing no less than every three months, and
   d. Downtime and malfunction procedures to ensure the timely provision of medication to the long-term care facility resident, and
2. Maintain documentation of the requirements of subsections (F)(1)(b) and (F)(1)(c) for inspection by the Board or its staff for not less than two years.

G. The Board may prohibit a pharmacy permittee or pharmacist-in-charge from using an automated dispensing system in a long-term care facility if the pharmacy permittee or the pharmacy permittee's employees do not comply with the requirements of subsections (A) through (F).

R4-23-702. ~~Repealed~~ Hospice Inpatient Facilities

A. If a pharmacy permittee contracts to provide pharmacy services to the patients of a hospice inpatient facility as defined in R4-23-110, the pharmacy permittee shall ensure that:

1. A prescription medication is provided only by a valid prescription order for an individual hospice inpatient facility patient, properly labeled for that patient, as specified in this subsection. Nothing in this section shall prevent a provider pharmacy from supplying non-prescription drugs in a manufacturer's unopened container;
2. A prescription medication label for a hospice inpatient facility patient complies with A.R.S. §§ 32-1968 and 36-2525 and contains:
   a. The drug name, strength, dosage form, and quantity; and
   b. The beyond-use date; and
3. If the label on the hospice inpatient facility patient's drug container becomes damaged or soiled, a pharmacist employed by the pharmacy that dispensed the drug container, through the exercise of professional judgment, may relabel the drug container. Only a pharmacist is permitted to label a drug container or alter the label of a drug container.

B. A pharmacist may help hospice inpatient facility personnel develop written policies and procedures for the procurement, administration, storage, control, recordkeeping, and disposal of drugs in the facility.

C. The provider pharmacy may contract with the hospice inpatient facility to provide pharmacist services at the facility that include evaluation of the patient's response to medication therapy, identification of potential adverse drug reactions, and recommended appropriate corrective action.

D. A provider pharmacy that places an emergency drug supply unit at a hospice inpatient facility shall comply with the requirements of R4-23-701.02.

E. A pharmacy shall not place an automated dispensing system as defined in R4-23-701.04 in a hospice inpatient facility.

F. Drugs previously dispensed to a patient of the hospice inpatient facility by another pharmacy, and drugs previously dispensed by the provider pharmacy, shall not be repackaged.

R4-23-703. Assisted Living Facilities

A. Assisted living facilities are licensed by the state Department of Health Services.

B. A pharmacy shall:

1. Only dispense, sell, or deliver a prescription or nonprescription drug to an assisted living facility resident after receiving a prescription order for the drug from the resident's medical practitioner;
2. Label, in accordance with A.R.S. §§ 32-1963.01 ~~and~~, 32-1968, and 36-2525, all drugs dispensed, sold, or delivered to an assisted living facility resident;
3. Obtain a copy of the current Arizona Department of Health Services license issued to an assisted living facility before dispensing drugs to that facility's resident; and
4. Maintain, for inspection by a Board compliance officer, a file containing the license copy required in subsection (B)(3).

C. In addition to the labeling requirements of A.R.S. §§ 32-1963.01, ~~and~~ 32-1968, and 36-2525, the label on a prescription medication for an assisted living facility resident shall include the name, strength, and quantity of the drug and a beyond-use date.

D. If the label on an assisted living facility resident's drug container becomes damaged or soiled, a pharmacist employed by the pharmacy that dispensed the drug container, through the exercise of professional judgment, may relabel the drug con-

tainer. Only a pharmacist is permitted to label a drug container or alter the label of a drug container.

E. A pharmacist may help assisted living facility personnel to develop written policies and procedures for the procurement, administration, storage, control, recordkeeping, and disposal of drugs in the facility and provide other information concerning drugs that assisted living facilities should have for safe and effective supervision of drug self-administration.

F. ~~A pharmacist shall not pay any rebate to an assisted living facility according to R4-23-404 and A.R.S. § 32-1932(B)(1).~~ A pharmacy shall not place an emergency drug supply unit as defined in R4-23-701.02 or an automated dispensing system as defined in R4-23-701.04 in an assisted living facility.

G. Drugs previously dispensed to a resident of the assisted living facility by another pharmacy, and drugs previously dispensed by the provider pharmacy, shall not be repackaged.

R4-23-704. ~~Repealed~~ Customized Patient Medication Packages

In lieu of dispensing two or more prescribed drugs in separate containers, a pharmacist may, with the consent of the patient, the patient's caregiver, the prescriber, or the facility caring for the patient, provide a customized patient medication package. The pharmacist preparing a customized patient medication package shall abide by the guidelines set forth in the current edition of the official compendium for labeling, packaging, and recordkeeping, and state and federal law.

NOTICE OF FINAL RULEMAKING

TITLE 4. PROFESSIONS AND OCCUPATIONS

CHAPTER 23. BOARD OF PHARMACY

[R13-153]

PREAMBLE

1. Articles, Parts, or Sections Affected (as applicable) — **Rulemaking Action**

R4-23-201	Amend
R4-23-202	Amend
R4-23-203	Amend
R4-23-301	Amend
R4-23-304	Amend
R4-23-1102	Amend
R4-23-1103	Amend

2. Citations to the agency's statutory rulemaking authority to include the authorizing statute (general) and the implementing statute (specific):

Authorizing statute: A.R.S. §§ 32-1904(A)(1) and (5) and 32-1904(B)(7), (9), and (10).

Implementing statute: A.R.S. §§ 32-1922, 32-1923, 32-1923.01, 32-1924, 32-1925, 32-1926, 32-1933, and 32-1935.

3. The effective date of the rule:

November 10, 2013

4. Citations to all related notices published in the *Register* as specified in R1-1-409(A) that pertain to the record of the final rulemaking package:

Notice of Rulemaking Docket Opening: 19 A.A.R. 524, March 15, 2013

Notice of Proposed Rulemaking: 19 A.A.R. 752, April 19, 2013

5. The agency's contact person who can answer questions about the rulemaking:

Name: Sandra Sutcliffe, Compliance Officer

Address: Board of Pharmacy
P.O. Box 18520
Phoenix, AZ 85005-8520

Telephone: (602) 771-2727

Fax: (602) 771-2749

E-mail: ssutcliffe@azpharmacy.gov

Web site: www.azpharmacy.gov

6. An agency's justification and reason why a rule should be made, amended, repealed, or renumbered, to include an explanation about the rulemaking:

In recent years the Board has added an online licensing link that allows for electronic application submission for pharmacists, interns, pharmacy technicians, and pharmacy technician trainees. The NABP has also changed to an online-only registration process for pharmacist licensure testing and jurisprudence testing. The Board has determined that several sections of the rules need to be amended to reflect changes in the application, registration, and licensure processes.

In addition, the results from the 2013 auditor's review from the State of Arizona Office of the Auditor General recommended the Board should track it's compliance with statutorily required time-frames for issuing licenses. In consultation with the Board's attorney, the Board staff reviewed all application and licensure processes including disposition of applications submitted with incomplete documentation and disposition of applications disclosing previous felony convictions or previous disciplinary actions by a licensing board. As a result, the Board has determined the time-frames for administrative and substantive review of license applications need to be amended to allow for a longer time-frame for applicants to provide missing documentation such as transcripts and intern hours, and to allow for a longer time-frame for substantive review for those applicants who are required to appear in front of the Board. The time-frames for administrative and substantive review will be amended to be consistent for all applicants for licensure.

The rulemaking will amend R4-23-201, General, by adding the requirement that a pharmacy permittee or pharmacist-in-charge verify a person has a current pharmacist license issued by the Board before that person practices as a pharmacist. Those references are in R4-23-201(E).

The rulemaking will amend R4-23-202, Licensure by Examination, by adding the requirement that a degree in pharmacy shall be from a school or college of pharmacy approved by the Board as specified in A.R.S. 32-1935, and includes the current name for the accreditation group for pharmacy professional programs. Those references are in R4-23-202(A). The rulemaking will add the requirements for the electronic application process, and remove the manual registration language from the sections on the NABP. The rulemaking will add the requirement that the Board will deem a passing score on the NAPLEX or MPJE invalid after 24 months from the applicant's examination date for those applicants that do not complete the licensure process within the 24 month period. Those references are in R4-23-202(B) and (C). The rulemaking moves the NAPLEX score transfer date information from subsection (B). Those references are in R4-23-202(D). The rulemaking will add the requirement a licensee maintains the certificate of licensure in the practice site as specified in A.R.S. 32-1933. Those references are in R4-23-202(E). The rulemaking will amend the time-frame requirements for the administrative and substantive reviews. Those references are in R4-23-202(F). The rulemaking will add a new section for license renewals as specified in A.R.S. 32-1925. Those references are in R4-23-202(G).

The rulemaking will amend R4-23-203, Licensure by Reciprocity, by adding the electronic application process, and removing the manual registration form language from the sections on the NABP. The rulemaking will add the requirement that the Board will deem a passing score on the MPJE invalid after 24 months from the applicant's examination date for those applicants that do not complete the licensure process within the 24 month period. Those references are in R4-23-203(B) and (C). The rulemaking will add the requirement a licensee maintain their certificate of licensure in the practice site as specified in ARS 32-1933. Those references are in R4-23-203(D).

The rulemaking will amend R4-23-301, Intern Licensure, by adding that written requests to the Board for waiver of intern licensure requirements and for approval to continue working as an intern when the intern licensee stops attending pharmacy school classes are to be done as specified in R4-23-401. Those references are in R4-23-301(A) and (C). The rulemaking updates language to make the rules more clear and concise, and changes the intern qualification section to verification of license to be consistent with other licensee sections. Those references are in R4-23-301(D) and (G). The rulemaking adds the requirements for the electronic application process. Those references are in R4-23-301(H). The rulemaking will add to the licensure section the "open" and "pending" status information found on the license verification site. The rulemaking will add the requirement that a licensee maintains the certificate of licensure in the practice site as specified in A.R.S. 32-1933. Those references are in R4-23-301(I). The rulemaking will change the time-frames for licensure to those specified in R4-23-202(F). Those references are in R4-23-301(J).

The rulemaking will amend R4-23-304 Reports by removing the requirement the Board provide written acknowledgment of receipt of reports and notification of the remaining intern hours needed for licensure. Those references are in R4-23-304(B)(1).

The rulemaking will amend R4-23-1102, Pharmacy Technician Licensure, by adding an eligibility section header and an application section that includes the electronic application process. Those references are in R4-23-1102(A) and (B). The rulemaking will add to the licensure section a reference to the "open" and "pending" status information found on the license verification site. The rulemaking will add the requirement that a licensee maintains the certificate of licensure or renewal certificate of licensure in the practice site as specified in A.R.S. 32-1933. Those references are in R4-23-1102(C) and (D). The rulemaking will change the time-frames for licensure to those specified in R4-23-202(F). Those references are in R4-23-1102(E). The rulemaking will add the requirement that a pharmacy permittee or pharmacist-in-charge verify a person has a current pharmacy technician license issued by the Board before that person practices as a pharmacy technician. Those references are in R4-23-1102(F).

The rulemaking will amend R4-23-1103, Pharmacy Technician Trainee Licensure, by adding an eligibility section header and an application section that includes the electronic application process. Those references are in R4-23-1103(A) and (B). The rulemaking will add to the licensure section a reference to the "open" and "pending" status information found on the license verification site. The rulemaking will add the requirement that a licensee maintains the certificate of licensure in the practice site as specified in A.R.S. 32-1933. Those references are in R4-23-1103(C). The rulemaking will add the application form and fee requirements for re-application for licensure. Those references are in R4-23-1103(D). The rulemaking will change the time-frames for licensure to those specified in R4-23-202(F). Those references are in R4-23-1103(E). The rulemaking will add the requirement that a pharmacy permittee or pharmacist-in-charge verify a person has a current pharmacy technician trainee license issued by the Board before that person practices as a pharmacy technician trainee. Those references are in R4-23-1103(F).

The rules will include format, style, and grammar necessary to comply with the current rules of the Secretary of State and the Governor's Regulatory Review Council.

7. A reference to any study relevant to the rules that the agency reviewed and either relied on or did not rely on in its evaluation of or justification for the rules, where the public may obtain or review each study, all data underlying each study, and any analysis of each study and other supporting material:

The agency did not review or rely on any study relevant to the rule.

8. A showing of good cause why the rulemaking is necessary to promote a statewide interest if the rulemaking will diminish a previous grant of authority of a political subdivision of this state:

Not applicable.

9. The summary of the economic, small business, and consumer impact:

The amended rules will impact the Board, pharmacies, pharmacists, interns, pharmacy technicians and pharmacy technician trainees. The amended rules' impact on the Board will be the usual rulemaking-related costs, which are minimal.

The Board estimates the amended rules will have minimal economic impact on pharmacies, pharmacists, interns, pharmacy technicians, and pharmacy technician trainees. The rulemaking reflects current application, registration, and licensing processes already in place with the Board and the NABP. Applicants that do not complete the licensure process within the time-frames set out in rule will have to submit a new form and fee to continue with the licensure process, and may have additional registration fees with the NABP.

For license verification, the Board maintains a license verification link on the web site, and verbal or written verification of license status is available by contacting Board office personnel.

The Board believes that approval of the rules benefits the public, pharmacies, pharmacists, interns, pharmacy technicians, and pharmacy technician trainees by establishing clear standards governing application and licensure processes for pharmacists, interns, pharmacy technicians, and pharmacy technician trainees.

We could not find a less intrusive or less costly alternative method to achieve the final rulemaking. The method we chose imposes minimal costs on the agency and pharmacies. The only alternative available is to not do the rulemaking, which would leave outdated application and licensure processes in rule.

10. A description of any changes between the proposed rulemaking, to include supplemental notices, and the final rulemaking:

There are no substantial changes in the final rules from the proposed rules. There are minor changes to style, format, grammar, and punctuation requested by G.R.R.C. staff.

11. An agency's summary of the public or stakeholder comments made about the rulemaking and the agency response to the comments:

A public hearing was held on May 28, 2013. No one attended the public hearing. The Board received one written comment from Janet Underwood, representing The Arizona Community Pharmacy Committee, voicing support for the rulemaking. No other comments were received.

12. All agencies shall list any other matters prescribed by statute applicable to the specific agency or to any specific rule or class of rules. Additionally, an agency subject to Council review under A.R.S. §§ 41-1052 and 41-1055 shall respond to the following questions:

a. Whether the rule requires a permit, whether a general permit is used and if not, the reasons why a general permit is not used:

The licenses referenced in this rulemaking are required by A.R.S. §§ 32-1922, 32-1923, and 32-1923.01. These licenses arguably fall within the definition of "general permit" found in A.R.S. § 41-1001(10). Therefore, the Board believes the proposed rules are written in accordance with A.R.S. § 41-1037.

b. Whether a federal law is applicable to the subject of the rule, whether the rule is more stringent than federal law and if so, citation to the statutory authority to exceed the requirements of federal law:

No, there is no applicable federal law.

c. Whether a person submitted an analysis to the agency that compares the rule's impact of the competitiveness

of business in this state to the impact on business in other states:
No.

13. A list of any incorporated by reference material as specified in A.R.S. § 41-1028 and its location in the rules:
None.

14. Whether the rule was previously made, amended, or repealed as an emergency rule. If so, cite the notice published in the *Register* as specified in R1-1-409(A). Also, the agency shall state where the text was changed between the emergency and the final rulemaking packages:
No.

15. The full text of the rules follows:

TITLE 4. PROFESSIONS AND OCCUPATIONS

CHAPTER 23. BOARD OF PHARMACY

ARTICLE 2. PHARMACIST LICENSURE

Section
R4-23-201. General
R4-23-202. Licensure by Examination
R4-23-203. Licensure by Reciprocity

ARTICLE 3. INTERN TRAINING AND PHARMACY INTERN PRECEPTORS

Section
R4-23-301. Intern Licensure
R4-23-304. Reports

ARTICLE 11. PHARMACY TECHNICIANS

Section
R4-23-1102. Pharmacy Technician Licensure
R4-23-1103. Pharmacy Technician Trainee Licensure

ARTICLE 2. PHARMACIST LICENSURE

R4-23-201. General

A. License required. Before practicing as a pharmacist in Arizona, a person shall possess a valid pharmacist license issued by the Board. There is no temporary licensure.

B. Methods of licensure. Licensure as a pharmacist shall be either:
1. By practical examination, using paper and pencil written testing, computer adaptive testing, or other Board-approved testing method; or
2. By reciprocity.

C. Practicing pharmacist holding a delinquent license. Before the Board reinstates an Arizona pharmacist license, a pharmacist, whose Arizona pharmacist license is delinquent for five or more years and who is practicing pharmacy outside the Board's jurisdiction with a pharmacist license issued by another jurisdiction, shall:
1. Pass the MPJE or other Board-approved jurisprudence examination,
2. Pay all delinquent annual renewal fees, and
3. Pay penalty fees.

D. Non-practicing pharmacist holding a delinquent license. Before the Board reinstates an Arizona pharmacist license, a pharmacist, whose Arizona pharmacist license is delinquent for five or more years and who did not practice pharmacy within the last 12 months before seeking reinstatement, shall:
1. Complete the requirements in subsection (C), and
2. Appear before the Board to furnish satisfactory proof of fitness to be licensed as a pharmacist.

E. Verification of license. A pharmacy permittee or pharmacist-in-charge shall not permit a person to practice as a pharmacist until the pharmacy permittee or pharmacist-in-charge verifies that the person is currently licensed by the Board as a pharmacist.

R4-23-202. Licensure by Examination

A. Eligibility. To be eligible for licensure as a pharmacist by examination, a person shall:
1. Have ~~an undergraduate~~ a degree in pharmacy from a school or college of pharmacy approved by the Board as speci-

fied in A.R.S. § 32-1935, and whose professional degree program, at the time the person graduates, is accredited by the ~~American Council on Pharmaceutical Education~~ Accreditation Council for Pharmacy Education; or

2. Qualify under the requirements of A.R.S. § 32-1922(D); and
3. Complete not less than 1500 hours of intern training as specified in R4-23-303.

B. Application.

1. An applicant for licensure by examination shall ~~file with the Board office~~:
   a. ~~A~~ Submit a completed application for licensure by examination ~~form,~~ electronically or manually on a form furnished by the Board, and
   b. ~~A completed NAPLEX registration form or ensure receipt of an official NABP score transfer report through the Board office online computer link with NABP indicating the applicant's score on the NAPLEX taken in another jurisdiction, and~~ Submit with the application form:
      i. The documents specified in the application form, and
      ii. The application fee specified in R4-23-205(C).
   ~~c. A completed MPJE registration form.~~
2. The Board office shall deem an application ~~or registration form received on the date that the Board office stamps on the form when the Board office receives the form~~ form received on the date the Board office electronically or manually date-stamps the form. ~~The Board office shall deem a score transfer received on the date that the NABP transmits the applicant's official NABP score transfer report through the online computer link to the Board office.~~
3. ~~An applicant for licensure by examination shall:~~
   ~~a. Make application on a form furnished by the Board, and~~
   ~~b. Submit with the application for licensure by examination form:~~
      ~~i. The documents specified in the application form, and~~
      ~~ii. The application fee specified in R4-23-205(C) made payable to the Arizona State Board of Pharmacy by money order or certified or personal check.~~

~~4.~~3. An applicant for licensure by examination shall~~:~~
   ~~a.~~ ~~Register~~ register for NAPLEX and MPJE ~~on forms furnished by the Board or NABP; and~~ through NABP's registration process.
   ~~b. Submit with the registration forms:~~
      ~~i. The documents specified in the registration forms, and~~
      ~~ii. The application fee specified by and made payable to NABP by money order, certified check, or bank draft.~~

~~5.~~4. The Board shall deem an application for licensure by examination ~~or a NAPLEX or MPJE registration to be~~ invalid after 12 months from the date the ~~Board office determines an application or registration form is complete~~ application is received. An applicant whose application ~~or registration~~ form is invalid and who wishes to continue licensure procedures, shall submit a new application ~~or registration~~ form and fee as specified in R4-23-205(C).

C. Passing grade; notification; re-examination.

1. To pass the required examinations, an applicant shall obtain a score of at least 75 on both the NAPLEX and MPJE.
2. The Board office shall:
   a. Retrieve an applicant's NAPLEX and MPJE score from the NABP ~~online~~ database no later than two weeks after the applicant's examination date~~.~~, and
   b. ~~Mail an applicant's NAPLEX and MPJE score to the applicant~~ Provide written notice by mail to an applicant who fails the NAPLEX or MPJE no later than seven days after the Board office ~~receives~~ retrieves the applicant's score from NABP.
3. An applicant who fails the NAPLEX or MPJE may ~~apply~~ register with the NABP to retake the examination within the 12-month period defined in subsection (B)~~(5)~~(4). ~~An applicant applying to retake an examination shall submit to the Board office a completed NAPLEX or MPJE registration form and pay the examination fee specified by and made payable to NABP by money order, certified check, or bank draft.~~ An applicant who fails the NAPLEX or MPJE three times shall petition the Board ~~for permission~~ as specified in R4-23-401 for Board approval before retaking the examination.
4. For the purpose of licensure by examination, the Board office shall deem a passing score on the NAPLEX or MPJE invalid after 24 months from the applicant's examination date. An applicant who fails to complete the licensure process within the 24-month period, and who wishes to continue licensure procedures, shall retake the examination(s).

D. NAPLEX score transfer.

1. The Board office shall deem a score transfer received on the date the NABP transmits the applicant's official score transfer report to the Board office.

~~1.~~2. An applicant who receives a passing score on the NAPLEX taken in another jurisdiction shall, within 12 months from the date the Board office receives the applicant's official NABP score transfer report from the NABP, make application for licensure according to subsection (B). After 12 months, an applicant may reapply for licensure in this state under the provisions of subsection (B) or R4-23-203(B).

~~2.~~3. An applicant who takes the NAPLEX in another jurisdiction and fails the examination may apply for licensure in this

state under the provisions of subsection (B).

E. Licensure. ~~The Board office shall issue a certificate of licensure to a successful applicant upon receipt of the licensure fee specified in R4-23-205(A)(1)(a). The Board office shall:~~

1. ~~Provide a receipt for payment of the licensure fee to an applicant who delivers a payment in person, or~~ The Board office shall issue a certificate of licensure and a wall license to a successful applicant upon receipt of:
   a. The initial licensure fee specified in R4-23-205(A)(1)(a), and
   b. The wall license fee specified in R4-23-205(E)(1)(a).
2. ~~Mail a receipt for payment of the licensure fee to an applicant within one working day of receiving the payment by mail or other delivery service.~~ A licensee shall maintain the certificate of licensure in the practice site for inspection by the Board or its designee or review by the public.

F. Time-frames for licensure by examination.

1. The Board office shall complete an administrative completeness review within ~~20~~ 60 days from the date ~~of receipt of an application or registration form~~ the application form is received.
   a. The Board office shall issue a written notice of administrative completeness to the applicant if no deficiencies are found in the application ~~or registration~~ form.
   b. If the application ~~or registration~~ form is incomplete, the Board office shall provide the applicant with a written notice that includes a comprehensive list of the missing information. The ~~20~~ 60-day time-frame for the Board office to finish the administrative completeness review is suspended from the date the notice of incompleteness is served until the applicant provides the Board office with all missing information.
   c. If the Board office does not provide the applicant with written notice regarding administrative completeness, the application ~~or registration~~ form shall be deemed complete ~~20~~ 60 days after receipt by the Board office.
2. An applicant with an incomplete application ~~or registration~~ form shall submit all of the missing information within ~~30~~ 90 days of service of the notice of incompleteness.
   a. If an applicant cannot submit all missing information within ~~30~~ 90 days of service of the notice of incompleteness, the applicant may send a written request for an extension to the Board office postmarked or delivered no later than ~~30~~ 90 days from service of the notice of incompleteness.
   b. The written request for an extension shall document the reasons the applicant is unable to meet the ~~30~~ 90-day deadline.
   c. The Board office shall review the request for an extension of the ~~30~~ 90-day deadline and grant the request if the Board office determines that an extension of the deadline will enable the applicant to assemble and submit the missing information. An extension shall be for no more than 30 days. The Board office shall notify the applicant in writing of its decision to grant or deny the request for an extension. ~~An applicant who requires an additional extension shall submit an additional written request according to this subsection.~~
3. If an applicant fails to submit a complete application ~~or registration~~ form within the time allowed, the Board office shall close the applicant's file. An applicant whose file is closed and who later wishes to obtain a license shall apply again according to subsection (B).
4. The Board office shall complete a substantive review of the applicant's qualifications in no more than ~~20~~ 120 days from the date on which the administrative completeness review of an application or registration form is complete.
   a. If an applicant is found to be ineligible for licensure by examination, the Board office shall issue a written notice of denial to the applicant.
   b. If an applicant is found to be eligible to take the NAPLEX, the Board office shall ~~issue a written notice of eligibility to the applicant and the NABP~~ notify the NABP that the applicant is eligible to test. The NABP shall issue the applicant an authorization to test letter.
   c. If an applicant is found to be eligible to take the MPJE, the Board office shall ~~issue a written notice of eligibility to the applicant and the NABP~~ notify the NABP that the applicant is eligible to test. The NABP shall issue the applicant an authorization to test letter.
   d. The Board office shall deem an applicant's eligibility to test invalid after 12 months from the date the application for licensure by examination is received.
   ~~d.~~e. If the Board office finds deficiencies during the substantive review of an application ~~or registration~~ form, the Board office shall issue a written request to the applicant for additional documentation.
   ~~e.~~f. The ~~20~~ 120-day time-frame for a substantive review of eligibility to take the NAPLEX or MPJE is suspended from the date of a written request for additional documentation until the date that all documentation is received. The applicant shall submit the additional documentation according to subsection (F)(2).
   ~~f.~~g. If the applicant and the Board office mutually agree in writing, the ~~20~~ 120-day substantive review time-frame may be extended once for no more than ~~10~~ 45 days.
5. For the purpose of A.R.S. § 41-1072 et seq., the Board establishes the following time-frames for licensure by examination.
   a. Administrative completeness review time-frame: ~~20~~ 60 days.
   b. Substantive review time-frame: ~~20~~ 120 days.

c. Overall time-frame: ~~40~~ 180 days.

G. License renewal.

1. To renew a license, a pharmacist shall submit a completed license renewal application electronically or manually on a form furnished by the Board with the biennial renewal fee specified in R4-23-205(A)(1)(b).
2. If the biennial renewal fee is not paid by November 1 of the renewal year specified in A.R.S. § 32-1925, the pharmacist license is suspended and the licensee shall not practice as a pharmacist. The licensee shall pay a penalty as provided in A.R.S. § 32-1925 and R4-23-205(G)(1) to vacate the suspension.
3. A licensee shall maintain the renewal certificate of licensure in the practice site for inspection by the Board or its designee or review by the public.
4. Time-frames for license renewals. The Board office shall follow the time-frames established in subsection (F).

R4-23-203. Licensure by Reciprocity

A. Eligibility. A person is eligible for licensure by reciprocity who:

1. Is licensed as a pharmacist in a jurisdiction that provides reciprocity to Arizona licensees~~;~~,
2. Has passed the NABPLEX or NAPLEX with a score of 75 or better or was licensed by examination in another jurisdiction having essentially the same standards for licensure as this state at the time the pharmacist was licensed~~;~~,
3. Provides evidence to the Board of having completed the required secondary and professional education and training specified in R4-23-202(A)~~;~~,
4. Has engaged in the practice of pharmacy for at least one year or has met the internship requirements of Article 3 within the year immediately before the date of application~~;~~, and
5. Has actively practiced as a pharmacist for 400 or more hours within the last calendar year or has an Arizona graduate intern license and has completed 400 hours of internship training in a Board-approved internship training site.

B. Application.

1. An applicant for licensure by reciprocity shall ~~file with the Board office~~:
   a. ~~A~~ Submit a completed application for licensure by reciprocity ~~form;~~ electronically or manually on a form furnished by the Board, and
   b. ~~A completed MPJE registration form.~~ Submit with the application form:
      i. The documents specified in the application form, and
      ii. The reciprocity fee specified in R4-23-205(B).
2. The Board office shall deem an application ~~or registration form received on the date that the Board office stamps on the application or registration form when the Board office receives the form~~ form received on the date the Board office electronically or manually date-stamps the form.
3. ~~An applicant for licensure by reciprocity shall:~~
   ~~a. Make application on a form furnished by the Board, and~~
   ~~b. Submit with the application for licensure by reciprocity form:~~
      ~~i. The documents specified in the application form, and~~
      ~~ii. The reciprocity and specified in application fee R4-23-205(B) and (C) and made payable to the Arizona State Board of Pharmacy by money order or certified or personal check.~~

~~4.~~3. An applicant for licensure by reciprocity shall~~:~~
   a. ~~Register~~ register for MPJE ~~on a form furnished by the Board or NABP; and~~ through NABP's registration process.
   b. ~~Submit with the registration form:~~
      ~~i. The documents specified in the registration form; and~~
      ~~ii. The application fee specified by and made payable to NABP by money order, certified check, or bank draft.~~

~~5.~~4. The Board office shall deem an application for licensure by reciprocity ~~form or MPJE registration~~ invalid after 12 months from the date the ~~Board office determines an application or registration form is complete~~ application is received. An applicant whose application ~~or registration~~ form is invalid and who wishes to continue licensure procedures, shall submit a new application ~~or registration~~ form and fee as specified in R4-23-205(B).

C. Passing grade; notification; re-examination.

1. To pass the required examination, an applicant shall obtain a score of at least 75 on the MPJE.
2. The Board office shall:
   a. Retrieve an applicant's MPJE score from the NABP ~~online~~ database no later than two weeks after the applicant's examination date~~;~~, and
   b. ~~Mail an applicant's MPJE score to the applicant~~ Provide written notice by mail to an applicant who fails the MPJE no later than seven days after the Board office ~~receives~~ retrieves the applicant's score from NABP.
3. An applicant who fails the MPJE may ~~apply~~ register with the NABP to retake the examination within the 12-month period specified in subsection (B)~~(5)~~(4). ~~An applicant applying to retake an examination shall submit to the Board office a completed MPJE registration form and pay the examination fee specified by and made payable to NABP by money order, certified check, or bank draft.~~ An applicant who fails the MPJE three times shall petition the Board ~~for permission~~ as specified in R4-23-401 for Board approval before retaking the examination.

4. For the purpose of licensure by reciprocity, the Board office shall deem a passing score on the MPJE invalid after 24 months from the applicant's examination date. An applicant who fails to complete the licensure process within the 24-month period, and who wishes to continue licensure procedures, shall retake the examination.

D. Licensure. ~~The Board office shall issue a certificate of licensure to a successful applicant upon receipt of the licensure fee specified in R4-23-205(A)(1)(a). The Board office shall:~~
1. ~~Provide a receipt for payment of the licensure fee to an applicant who delivers a payment in person; or~~ The Board office shall issue a certificate of licensure and a wall license to a successful applicant upon receipt of:
   a. The initial licensure fee specified in R4-23-205(A)(1)(a), and
   b. The wall license fee specified in R4-23-205(E)(1)(a).
2. ~~Mail a receipt for payment of the licensure fee to an applicant within one working day of receiving the payment by mail or other delivery service.~~ A licensee shall maintain the certificate of licensure in the practice site for inspection by the Board or its designee or review by the public.

E. Time-frames for licensure by reciprocity. The Board office shall follow the time-frames established for licensure by examination in R4-23-202(F).

F. License renewal. License renewal shall be the same as specified in R4-23-202(G).

ARTICLE 3. INTERN TRAINING AND PHARMACY INTERN PRECEPTORS

R4-23-301. Intern Licensure

A. Licensure as a pharmacy intern or graduate intern is for the purpose of complementing the individual's academic or experiential education in preparation for licensure as a pharmacist. An applicant may request a waiver of intern licensure requirements by submitting a written request as specified in R4-23-401 and appearing in person at a Board meeting.

B. The prerequisites for licensure as a pharmacy intern are:
1. Current enrollment, in good standing, in a Board-approved college or school of pharmacy; or
2. Graduation from a college or school of pharmacy that is not approved by the Board; and
3. Proof that the applicant is certified by the Foreign Pharmacy Graduate Examination Committee (FPGEC); or
4. By order of the Board if the Board determines the applicant needs intern training.

C. If a pharmacy intern licensee stops attending pharmacy school classes before completing the pharmacy school's requirements for graduation, the licensee shall immediately stop practicing as a pharmacy intern and surrender the pharmacy intern license to the Board or the Board's designee no later than 30 days after the date of the last attended class, unless the licensee ~~requests and is granted permission by the Board~~ petitions the Board as specified in R4-23-401 and receives Board approval to continue working as a pharmacy intern. A student re-entering a pharmacy program who wishes to continue internship training shall reapply for pharmacy intern licensure.

D. The prerequisites for licensure as a graduate intern are:
1. ~~Graduate~~ Graduation from a Board-approved college or school of pharmacy, and
2. ~~Apply~~ Application for licensure as a pharmacist by examination or reciprocity, or
3. By order of the Board if the Board determines that the applicant needs intern training.

E. Experiential training. Intern training shall include the activities and services encompassed by the term "practice of pharmacy" as defined in A.R.S. § 32-1901.

F. Out-of-state experiential training. An intern shall receive credit for intern training received outside this state if the Board determines that the intern training requirements of the jurisdiction in which the training was received are equal to the minimum requirements for intern training in this state. An applicant seeking credit for intern training received outside this state shall furnish a certified copy of the records of intern training from:
1. The Board of Pharmacy or the intern licensing agency of the other jurisdiction where the training was received; or
2. In a jurisdiction without an intern licensing agency, the director of the applicant's Board-approved college or school of pharmacy's experiential training program.

G. ~~Management required to verify intern's qualifications.~~ Verification of license. ~~An owner, manager,~~ A pharmacy permittee or pharmacist-in-charge shall not permit a person to ~~act~~ practice as a pharmacy or graduate intern until the ~~owner, manager,~~ pharmacy permittee or pharmacist-in-charge verifies that the person is currently licensed by the Board as a pharmacy or graduate intern.

H. Intern application. ~~An applicant for licensure as a pharmacy intern or graduate intern shall:~~
1. ~~Ensure that the applicant's college or school of pharmacy provides documentation to the Board of the applicant's current enrollment or graduation; and~~ An applicant for licensure as a pharmacy intern or graduate intern shall:
   a. Submit a completed application electronically or manually on a form furnished by the Board, and
   b. Submit with the application form:
      i. The documents specified in the application form,
      ii. The initial licensure fee specified in R4-23-205(A)(2), and
      iii. The wall license fee specified in R4-23-205(E)(1)(b).
2. ~~File an application on a form furnished by the Board, that includes:~~ The Board office shall deem an application form received on the date the Board office electronically or manually date-stamps the form.

~~a. Applicant's name, address, mailing address, if different, telephone number, and social security number;~~
~~b. Name and address of college or school of pharmacy attending or attended, degree anticipated or received, and anticipated date or date of graduation;~~
~~c. Whether the applicant has ever been convicted of an offense involving moral turpitude, a felony offense, or any drug-related offense or has any currently pending felony or drug-related charges, and if so, indicate charge, conviction date, jurisdiction, and location;~~
~~d. Whether the applicant has ever had an intern license revoked, suspended, or denied in this state or any other jurisdiction, and if so, indicate where and when;~~
~~e. If the applicant graduated from an unapproved college or school of pharmacy, a notarized copy of the applicant's Foreign Pharmacy Graduate Examination Committee (FPGEC) certification document;~~
~~f. Date signed and applicant's verified signature; and~~
~~g. The initial licensure fee specified in R4-23-205.~~

I. Licensure. ~~Within seven business days of receipt of a completed application, fees, and other information specified in subsection (H), the Board office shall determine whether an application is complete. If the application is complete, the Board office shall issue a license~~ number and mail a current renewal receipt to an applicant. ~~An applicant who is issued a license number may begin practice as a pharmacy intern or graduate intern. The initial licensure fee shall include the issuance of a wall certificate. The Board office shall mail the application is incomplete, the Board office shall issue a notice of incompleteness. An applicant with an incomplete application shall comply with the requirements of R4-23-202(F)(2) and (3).~~

1. If an applicant is found to be ineligible for intern licensure under statute and rule, the Board office shall issue a written notice of denial to the applicant.
2. If an applicant is found to be eligible for intern licensure under statute and rule, the Board office shall issue a certificate of licensure and a wall license. An applicant who is assigned a license number and who has been granted "open" status on the Board's license verification site may begin practice as a pharmacy intern or graduate intern prior to receiving the certificate of licensure.
3. An applicant who is assigned a license number and who has a "pending" status on the Board's license verification site shall not practice as a pharmacy intern or graduate intern until the Board office issues a certificate of licensure as specified in subsection (2).
4. A licensee shall maintain the certificate of licensure in the practice site for inspection by the Board or its designee or review by the public.

J. Time-frames for intern licensure. The Board office shall follow the time-frames established in R4-23-202(F).

~~J.~~K. License renewal. ~~A pharmacy intern whose license expires before the intern completes the education or training required for licensure as a pharmacist but less than six years after the issuance of the initial pharmacy intern license may renew the intern license for a period equal to the difference between the expiration date of the initial intern license and six years from the issue date of the initial intern license by payment of a prorated renewal fee based on the initial license fee specified in R4-23-205. If a pharmacy intern fails to graduate from a Board-approved college or school of pharmacy within six years from the date the Board issues the initial intern license, the intern is not eligible for relicensure as an intern unless the intern obtains Board approval as specified in A.R.S. § 32-1923(E). To remain in good standing, an intern who receives Board approval for relicensure shall pay a prorated renewal fee for the number of months of licensure approved by the Board based on the initial license fee specified in R4-23-205 before the license expiration date. If an intern receives Board approval for relicensure and does not pay the renewal fee specified in this subsection before the license expiration date, the intern license is suspended and the intern shall pay a penalty as provided in A.R.S. § 32-1925 to vacate the suspension.~~

1. A pharmacy intern whose license expires before the intern completes the education or training required for licensure as a pharmacist but less than six years after the issuance of the initial pharmacy intern license may renew the intern license for a period equal to the difference between the expiration date of the initial intern license and six years from the issue date of the initial intern license by payment of a prorated renewal fee based on the initial license fee specified in R4-23-205(A)(2).
2. If a pharmacy intern fails to graduate from a Board-approved college or school of pharmacy within six years from the date the Board issues the initial intern license, the intern is not eligible for relicensure as an intern unless the intern obtains Board approval as specified in A.R.S. § 32-1923(E) and R4-23-401. To remain in good standing, an intern who receives Board approval for relicensure shall pay a prorated renewal fee for the number of months of licensure approved by the Board based on the initial license fee specified in R4-23-205(A)(2) before the license expiration date.
3. If an intern receives Board approval for relicensure and does not pay the renewal fee specified in subsection (2) before the license expiration date, the intern license is suspended and the licensee shall not practice as an intern. The licensee shall pay a penalty as provided in A.R.S. § 32-1925 and R4-23-205(G)(1) to vacate the suspension.

~~K.~~L. Notification of training.

1. A pharmacy intern who is employed as an intern outside the experiential training program of a Board-approved college or school of pharmacy or a graduate intern shall notify the Board within ten days of starting or terminating training, or changing training site.

2. The director of a Board-approved college or school of pharmacy's experiential training program shall provide the Board an intern training report as specified in R4-23-304(B)(3).

R4-23-304. Reports

A. Change of employment or mailing address. A pharmacy intern or graduate intern shall notify the Board within ~~10~~ ten days of change of employment or mailing address.

B. Annual reports.

1. A pharmacy intern who is a graduate of a college or school of pharmacy that is not approved by the Board or is a graduate intern shall provide the Board annual intern training reports for the duration of training. The pharmacy intern shall file an annual intern training report on a report form provided by the Board by calendar year (January 1st through December 31st). An annual intern training report shall be received at the Board's office no later than 30 days after the end of the calendar year. ~~The Board shall write the intern to acknowledge receipt of the reports and notify the intern of the remaining hours of training necessary for licensure.~~ Any intern training hours reported to the Board office more than 30 days after the end of the calendar year in which the training hours were performed shall not be credited toward the total intern training hours required for licensure.
2. After graduation and before sitting for the NAPLEX or MPJE, a pharmacy intern who is a graduate of a Board-approved college or school of pharmacy shall ensure that the director of the Board-approved college or school of pharmacy's experiential training program provides the Board an intern training report that includes:
   a. The dates and number of training hours experienced, by training site and total; and
   b. The date signed and experiential training program director's signature verifying that the pharmacy intern successfully completed the experiential training program.

ARTICLE 11. PHARMACY TECHNICIANS

R4-23-1102. Pharmacy Technician Licensure

A. ~~Application~~ Eligibility. An applicant for licensure as a pharmacy technician shall~~:~~

~~1.~~ ~~Provide~~ provide the Board proof that the applicant is eligible under R4-23-1101(B)(2), including documentation that the applicant:

~~a.~~1. Completed a pharmacy technician training program that meets the standards prescribed in R4-23-1105(B)(2); and

~~b.~~2. Passed the Pharmacy Technician Certification Board (PTCB) examination or another Board-approved pharmacy technician examination; or

~~c.~~3. Meets the requirements of R4-23-1105(D)(1) or (2)~~:~~.

~~2. File an application on a form furnished by the Board, that includes:~~

~~a. Applicant's name, address, mailing address, if different, telephone number, and social security number;~~

~~b. Whether the applicant has ever been convicted of an offense involving moral turpitude, a felony offense, or any drug-related offense or has any currently pending felony or drug-related charge, and if so, indicate charge, charge date, conviction date, and jurisdiction;~~

~~c. Whether the applicant has ever had a pharmacy technician license revoked, suspended, or has a pending revocation or suspension action, or denied in this state or any other jurisdiction, and if so, indicate where and when;~~

~~d. Pharmacy name and address where the pharmacy technician will practice;~~

~~e. Date signed and applicant's verified signature; and~~

~~f. The wall license and initial licensure fees specified in R4-23-205.~~

B. Application.

1. An applicant for licensure as a pharmacy technician shall:
   a. Submit a completed application electronically or manually on a form furnished by the Board, and
   b. Submit with the application form:
      i. The documents specified in the application form,
      ii. The initial licensure fee specified in R4-23-205(A)(3)(a), and
      iii. The wall license fee specified in R4-23-205(E)(1)(c).
2. The Board office shall deem an application form received on the date the Board office electronically or manually date-stamps the form.

~~**B.**~~**C.** Licensure. ~~Within seven business days of receipt of a completed application, fees, and other information specified in subsection (A), the Board office shall determine whether the application is complete. If the application is complete, the Board shall assess whether the applicant is qualified under statute and rule. If the applicant is qualified, the Board office shall issue a license number and mail a license to the applicant. An applicant who is issued a license number may begin practice as a pharmacy technician. The Board office shall mail a wall license to the licensee within 14 days of issuing the license number.~~

1. If an applicant is found to be ineligible for pharmacy technician licensure under statute and rule, the Board office shall issue a written notice of denial to the applicant.
2. If an applicant is found to be eligible for pharmacy technician licensure under statute and rule, the Board office shall issue a certificate of licensure and a wall license. An applicant who is assigned a license number and who has been

granted "open" status on the Board's license verification site may begin practice as a pharmacy technician prior to receiving the certificate of licensure.

3. An applicant who is assigned a license number and who has a "pending" status on the Board's license verification site shall not practice as a pharmacy technician until the Board office issues a certificate of licensure as specified in subsection (2).
4. A licensee shall maintain the certificate of licensure in the practice site for inspection by the Board or its designee or review by the public.

~~C.~~**D.** License renewal. ~~To renew a license, a pharmacy technician shall submit a license renewal form supplied by the Board with the biennial renewal fee specified in R4-23-205. The Board office will process the application for renewal in the same manner described in subsection (B).~~

1. To renew a license, a pharmacy technician shall submit a completed license renewal application electronically or manually on a form furnished by the Board with the biennial renewal fee specified in R4-23-205(A)(3)(b).
2. If the biennial renewal fee is not paid by November 1 of the renewal year specified in A.R.S. § 32-1925, the pharmacy technician license is suspended and the licensee shall not practice as a pharmacy technician. The licensee shall pay a penalty as provided in A.R.S. § 32-1925 and R4-23-205(G)(1) to vacate the suspension.
3. A licensee shall maintain the renewal certificate of licensure in the practice site for inspection by the Board or its designee or review by the public.

~~D. If the biennial renewal fee is not paid by November 1 of the renewal year specified in A.R.S. § 32-1925, the pharmacy technician license is suspended and the licensee shall pay a penalty as provided in A.R.S. § 32-1925 and R4-23-205 to vacate the suspension.~~

E. Time-frames for pharmacy technician licensure and license renewal. The Board office shall follow the time-frames established in R4-23-202(F).

F. Verification of license. A pharmacy permittee or pharmacist-in-charge shall not permit a person to practice as a pharmacy technician until the pharmacy permittee or pharmacist-in-charge verifies that the person is currently licensed by the Board as a pharmacy technician.

R4-23-1103. Pharmacy Technician Trainee Licensure

A. ~~Application~~ Eligibility. An applicant for licensure as a pharmacy technician trainee shall~~:~~

~~1. Provide~~ provide the Board proof that the applicant is eligible under R4-23-1101(B)(1)~~; and~~.

~~2. File an application on a form furnished by the Board, that includes:~~

~~a. Applicant's name, address, mailing address, if different, telephone number, and social security number;~~
~~b. Whether the applicant has ever been convicted of an offense involving moral turpitude, a felony offense, or any drug-related offense or has any currently pending felony or drug-related charge, and if so, indicate charge, charge date, conviction date, and jurisdiction;~~
~~c. Whether the applicant has ever had a pharmacy technician or pharmacy technician trainee license revoked, suspended, or has a pending revocation or suspension action, or denied in this state or any other jurisdiction, and if so, indicate where and when;~~
~~d. Pharmacy name and address where the pharmacy technician trainee will complete the pharmacy technician training program;~~
~~e. Date signed and applicant's verified signature; and~~
~~f. The wall license and initial licensure fees specified in R4-23-205.~~

B. Application.

1. An applicant for licensure as a pharmacy technician trainee shall:
   a. Submit a completed application electronically or manually on a form furnished by the Board, and
   b. Submit with the application form:
      i. The documents specified in the application form,
      ii. The licensure fee specified in R4-23-205(A)(4), and
      iii. The wall license fee specified in R4-23-205(E)(1)(d).
2. The Board office shall deem an application form received on the date the Board office electronically or manually date-stamps the form.

~~B.~~**C.** Licensure.

~~1. Within seven business days of receipt of a completed application, fees, and other information specified in subsection (A), the Board office shall determine whether the application is complete. If the application is complete, the Board shall assess whether the applicant is qualified under statute and rule. If the applicant is qualified, the Board office shall issue a license number and mail a license to the applicant. An applicant who is issued a license number may begin practice as a pharmacy technician trainee. The Board office shall mail a wall license to the licensee within 14 days of issuing the license number. A pharmacy technician trainee license is valid for 24 months from the date issued.~~

~~2. A pharmacy technician trainee who does not complete the prescribed training program and pass the Pharmacy Technician Certification Board (PTCB) examination or another Board-approved pharmacy technician examination before the pharmacy technician trainee's license expires is not eligible for licensure as a pharmacy technician and shall not~~

~~practice as a pharmacy technician or pharmacy technician trainee.~~

1. If an applicant is found to be ineligible for pharmacy technician trainee licensure under statute and rule, the Board office shall issue a written notice of denial to the applicant.
2. If an applicant is found to be eligible for pharmacy technician trainee licensure under statute and rule, the Board office shall issue a certificate of licensure and a wall license. An applicant who is assigned a license number and who has been granted "open" status on the Board's license verification site may begin practice as a pharmacy technician trainee prior to receiving the certificate of licensure.
3. An applicant who is assigned a license number and who has a "pending" status on the Board's license verification site shall not practice as a pharmacy technician trainee until the Board office issues a certificate of licensure as specified in subsection (2).
4. A licensee shall maintain the certificate of licensure in the practice site for inspection by the Board or its designee or review by the public.
5. A pharmacy technician trainee license is valid for 24 months from the date issued. A pharmacy technician trainee who does not complete the prescribed training program and pass the Pharmacy Technician Certification Board (PTCB) examination or another Board-approved pharmacy technician examination before the pharmacy technician trainee's license expires is not eligible for licensure as a pharmacy technician and shall not practice as a pharmacy technician or pharmacy technician trainee.

~~C.~~**D.** Re-application for licensure.

1. The Board may allow a pharmacy technician trainee whose license expires before the pharmacy technician trainee completes the prescribed training program and passes the Pharmacy Technician Certification Board (PTCB) examination or another Board-approved pharmacy technician examination to reapply for licensure not more than one time. A pharmacy technician trainee whose license has expired may make a special request to the Board under R4-23-401 for approval to reapply for licensure.

~~D.~~2. The Board shall base its decision to grant or deny a special request to reapply for licensure on an assessment of:

~~1.~~a. The reasons the pharmacy technician trainee did not complete a pharmacy technician training program and the likelihood that the pharmacy technician trainee will complete a pharmacy technician training program within the next 24 months,

~~2.~~b. The reasons the pharmacy technician trainee failed the pharmacy technician examination and the likelihood that the pharmacy technician trainee will pass the pharmacy technician examination within the next 24 months, and

~~3.~~c. Other extenuating circumstances.

3. A pharmacy technician trainee that receives Board approval to reapply for licensure shall submit a completed application manually on a form furnished by the Board and pay the licensure fee specified in R4-23-205(A)(4).

E. Time-frames for pharmacy technician trainee licensure. The Board office shall follow the time-frames established in R4-23-202(F).

F. Verification of license. A pharmacy permittee or pharmacist-in-charge shall not permit a person to practice as a pharmacy technician trainee until the pharmacy permittee or pharmacist-in-charge verifies that the person is currently licensed by the Board as a pharmacy technician trainee.